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No.

In the Supreme Court of the United States

OCTOBER TERM, 1980

UNITED STATES OF AMERICA, PETITIONER

v.

ERIKA, INC.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF CLAIMS

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QUESTION PRESENTED

Whether the Court of Claims has jurisdiction under 28 U.S.C. 1491 to review administrative determinations of the amount of benefits payable under Part B of the Medicare Act, 42 U.S.C. 1395j *et seq.*

TABLE OF CONTENTS

	Page
Opinion below	1
Jurisdiction	1
Statutes involved	2
Statement	4
Reasons for granting the petition	12
Conclusion	21
Appendix A	1a
Appendix B	29a
Appendix C	30a
Appendix D	34a
Appendix E	51a
Appendix F	53a
Appendix G	89a

TABLE OF AUTHORITIES

Cases:

Bussey v. *Harris*, 611 F.2d 1001	20
Califano v. *Sanders*, 430 U.S. 99	18
Chelsea Community Hospital v. *Michigan Blue Cross Ass'n*, 630 F.2d 1131	20
Drennan v. *Harris*, 606 F.2d 846	20
Eastport S.S. Corp. v. *United States*, 372 F.2d 1002	17
Fedorenko v. *United States*, No. 79-5602 (Jan. 21, 1981)	13
Goldstein v. *United States*, 201 Ct. Cl. 888, cert. denied, 414 U.S. 974	16
Johnson v. *Robison*, 415 U.S. 361	15, 17
Kechijian v. *Califano*, 621 F.2d 1	20, 21
Dr. John T. MacDonald Foundation, Inc. v. *Califano*, 571 F.2d 328, cert. denied, 439 U.S. 893	20
Muehlen v. *United States*, 209 Ct. Cl. 690	19

Cases—Continued Page

St. Louis University v. *Blue Cross Hospital Service*, 537 F.2d 283, cert. denied, 429 U.S. 977 ..... 20, 21
Szekely v. *Florida Medical Ass'n*, 517 F.2d 345, cert. denied, 425 U.S. 960 12
Trinity Memorial Hospital v. *Associated Hospital Service, Inc.*, 570 F.2d 660 20
United States v. *Hopkins*, 427 U.S. 123 17
United States v. *King*, 395 U.S. 1 ..... 17, 19
United States v. *Mitchell*, 445 U.S. 535 ..... 16, 17
United States v. *Testan*, 424 U.S. 392 ..... 16, 17, 19
Whitecliff, Inc. v. *United States*, 536 F.2d 347, cert. denied, 430 U.S. 969 ..... 9, 17, 19, 20

Constitution, statutes and regulations:

United States Constitution:
Fifth Amendment 8, 9, 19
Social Security Act, 42 U.S.C. (& Supp. III) 301 *et seq.*:
Section 205(b), 42 U.S.C. 405(b) 5
Section 205(g), 42 U.S.C. 405(g) 5, 18
Section 205(h), 42 U.S.C. (1970 ed.) 405(h) .. 3, 6, 18, 20
Section 205(h), 42 U.S.C. 405(h) 14, 16
Health Insurance for the Aged and Disabled Act (Medicare Act), 42 U.S.C. 1395 *et seq.*:
42 U.S.C. (& Supp. III) 1395c to 1395i-2 4
42 U.S.C. 1395d 4
42 U.S.C. 1395f 4
42 U.S.C. 1395g 4
42 U.S.C. (& Supp. III) 1395h 4, 5
42 U.S.C. 1395j *et seq.* 4
42 U.S.C. (& Supp. III) 1395k 4
42 U.S.C. (& Supp. III) 1395*l* 4, 7
42 U.S.C. 1395u 4
42 U.S.C. 1395u(a) 6
42 U.S.C. 1395u(a)(1)(A) 4, 7
42 U.S.C. 1395u(a)(1)(B) 4

Constitution, statutes and regulations—Continued Page

42 U.S.C. (& Supp. III) 1395u(b)(3) 4, 7, 10
42 U.S.C. 1395u(b)(3)(C) 6, 8, 13, 14
42 U.S.C. 1395x(u) 4
42 U.S.C. 1395ff 2, 4, 5, 9, 10, 12, 14, 16, 19
42 U.S.C. (1970 ed.) 1395ff 15
42 U.S.C. 1395ff(a) 5
42 U.S.C. 1395ff(b) 15
42 U.S.C. 1395ff(b)(2) 5, 13, 15
42 U.S.C. 1395ii 3, 6
42 U.S.C. 1395j *et seq.* 4
42 U.S.C. 1395*oo* 5, 19
42 U.S.C. 1395*oo*(a) 5, 6
42 U.S.C. 1395*oo*(f) 6
42 U.S.C. 1395pp(d) 5

Tucker Act:

28 U.S.C. (& Supp. III) 1346(a)(2) 18
28 U.S.C. 1491 .....9, 12, 17, 19
28 U.S.C. (& Supp. III) 1491 ..... 3, 16
28 U.S.C. (& Supp. III) 2415 18

Pub. L. No. 92-603, Section 243(a), 86 Stat. 1420.. 5
Pub. L. No. 96-499, Section 946, 94 Stat. 2642..... 7
42 C.F.R.:

Section 405.406(b) (1979) 5
Section 405.704(a) 5
Section 405.801(a) 6
Section 405.807 *et seq.* 16

Miscellaneous:

118 Cong. Rec. 33992 (1972) 10, 15
H.R. Conf. Rep. No. 92-1605, 92d Cong., 2d Sess. (1972) 15
H.R. Rep. No. 213, 89th Cong., 1st Sess. (1965).... 13, 14
J. Rogers, *A Way Out Of The Social Security Jurisdiction Tangle*, 21 Ariz. L. Rev. 689 (1979).. 19
S. Rep. No. 404, 89th Cong., 1st Sess. (1965) 9, 13, 14

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UNITED STATES OF AMERICA, PETITIONER

v.

ERIKA, INC.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF CLAIMS

The Solicitor General, on behalf of the United States, petitions for a writ of certiorari to review the judgment of the United States Court of Claims in this case.

OPINION BELOW

The opinion of the Court of Claims (App. A, *infra*, 1a-28a) is reported at 634 F.2d 580. The decisions of the insurance carrier's hearing officer on respondent's claims under Counts I and II of the Supplemental Petition (App. D, *infra*, 34a-50a), the hearing officer's denial of respondent's request to reopen the hearing and reconsider that decision (App. E, *infra*, 51a-52a), and the hearing officer's decision on respondent's claims under Count III of its Supplemental Petition (App. F, *infra*, 53a-88a) are not reported.

JURISDICTION

The opinion of the Court of Claims was issued on October 22, 1980. An order removing the case from the Court of Claims' docket (App. B, *infra*, 29a) was en-

tered on October 24, 1980. The order on the government's motion for rehearing, clarifying aspects of the court's opinion (App. C, *infra*, 30a-33a), was entered on February 6, 1981. On January 12, 1981, the Chief Justice extended the time for filing a petition for a writ of certiorari to and including March 21, 1981. The jurisdiction of this Court is invoked under 28 U.S.C. 1255(1).

STATUTES INVOLVED

1. Section 1869 of the Social Security Act, 42 U.S.C. 1395ff, provides in pertinent part:

> (a) Entitlement to and amount of benefits.
>
> The determination of whether an individual is entitled to benefits under Part A or Part B, and the determinations of the amount of benefits under Part A, shall be made by the Secretary in accordance with regulations prescribed by him.
>
> (b) Appeal by individuals.
>
> (1) Any individual dissatisfied with any determination under subsection (a) of this section as to—
>
> (A) whether he meets the conditions of section 426 or section 426a of this title, or
>
> (B) whether he is eligible to enroll and has enrolled pursuant to the provisions of Part B of this subchapter, or section 1395i-2 of this title, or section 1819, or
>
> (C) the amount of benefits under Part A (including a determination where such amount is determined to be zero) shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title.
>
> (2) Notwithstanding the provisions of subparagraph (C) of paragraph (1) of this subsection, a hearing shall not be available to an individual by reason of such subparagraph (C) if the amount in controversy is less than $100; nor shall judicial review be available to an individual by reason of such

subparagraph (C) if the amount in controversy is less than $1,000.

2. Section 205(h) of the Social Security Act, incorporated into the Medicare Act through 42 U.S.C. 1395ii and codified at 42 U.S.C. (1970 ed.) 405(h), provides:

> The findings and decisions of the Secretary after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Secretary shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Secretary, or any officer or employee thereof shall be brought under section 41 of title 28 to recover on any claim arising under this subchapter.[1]

3. 28 U.S.C. (& Supp. III) 1491 provides in pertinent part:

> The Court of Claims shall have jurisdiction to render judgment upon any claim against the United States founded either upon the Constitution, or any Act of Congress, or any regulation of an executive department, or upon any express or implied contract with the United States, or for liquidated or unliquidated damages in cases not sounding in tort.
>
> * * * * *
>
> To provide an entire remedy and to complete the relief afforded by the judgment, the court may, as an incident of and collateral to any such judgment, issue orders directing restoration to office or position, placement in appropriate duty or retirement status, and correction of applicable records, and such orders may be issued to any appropriate official of the United States. In any case within its jurisdiction, the court shall have the power to remand appropriate matters to any administrative or executive body or

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[1] In the 1976 edition of the United States Code, which has not been enacted into positive law, the third sentence of Section 205(h) is changed to refer to "sections 1331 and 1346" of Title 28 rather than "section 41 of title 28," as in the Social Security Act itself.

official with such direction as it may deem proper and just.

STATEMENT

The issue in this case is whether the Court of Claims has jurisdiction under 28 U.S.C. (& Supp. III) 1491 to review the amount of benefits payable under Part B of the Health Insurance for the Aged and Disabled Act (commonly known as the Medicare Act), 42 U.S.C. 1395j *et seq.*, for particular medical and other health services. Before relating the facts of this case, we shall briefly describe the Medicare program and the provisions for administrative and judicial review of certain determinations made under the Act.

1.a. The Medicare program is divided into two parts. Part A of the Act, 42 U.S.C. (& Supp. III) 1395c to 1395i-2, provides insurance for hospital and related post-hospital services. 42 U.S.C. (& Supp. III) 1395c and 1395d. Payment for these services is made directly to the hospital or other provider of services. 42 U.S.C. 1395g. The amount of benefits payable to the provider is to be determined by the Secretary of Health and Human Services (HHS), 42 U.S.C. 1395f, 1395g and 1395x(u), although the Secretary is authorized to enter into a contract with a fiscal intermediary nominated by the provider, under which the intermediary will determine the amount of payments due and make these payments to the provider. 42 U.S.C. (& Supp. III) 1395h.

Part B of the Medicare Act provides a voluntary program of supplementary medical insurance covering, in general, 80% of the reasonable costs of certain other medical services—primarily physicians' services and such items as medical supplies, x-rays and laboratory tests. 42 U.S.C. (& Supp. III) 1395k and 1395*l*. Part B benefits are administered by insurance carriers pursuant to contracts entered into with the Secretary. 42 U.S.C. 1395u. The carrier determines the amount required to be paid under Part B and pays the benefit, generally either to the individual insured or to the physician or other supplier of services to whom the insured has assigned his benefits. 42 U.S.C. 1395u(a)(1)(A) and (B), 1395u(b)(3)(B).

b. The Medicare Act provides specific mechanisms for review of certain determinations made under the Act. Pursuant to 42 U.S.C. 1395ff, the Secretary must determine whether an individual is eligible for any benefits under Part A or Part B. If an individual is dissatisfied with the initial determination that he is ineligible for benefits, he is entitled under 42 U.S.C. 1395ff(b) to a hearing on that question by the Secretary as provided in 42 U.S.C. 405(b) and to judicial review of the Secretary's final decision as provided in 42 U.S.C. 405(g).

The Act also directs the Secretary to determine the amount of benefits under Part A (see 42 U.S.C. 1395ff(a); 42 C.F.R. 405.704(a)), although, as noted above, this determination is ordinarily made by a fiscal intermediary. 42 U.S.C. (& Supp. III) 1395h. If the individual beneficiary is dissatisfied with the determination regarding the amount of benefits to which he is entitled under Part A, the Act grants a right to a hearing by the Secretary under 42 U.S.C. 405(b) where the amount in controversy is $100 or more and a right of judicial review under 42 U.S.C. 405(g) where the amount in controversy is $1,000 or more. Review is expressly barred where these amount-in-controversy requirements are not satisfied. 42 U.S.C. 1395ff(b)(2). See also 42 U.S.C. 1395pp(d).

In addition to these rights of review at the behest of the individual beneficiary, a hospital or other provider of Part A services also has a right under 42 U.S.C. 1395*oo*[2] to obtain review of the total amount of reimbursements to which it is entitled for all services rendered during a particular year. That section states that if a provider is dissatisfied with the fiscal intermediary's determination, after reviewing the provider's annual cost report,[3] as to the total amount of reimbursement, and if the amount in controversy is at least $10,000, the provider is entitled to

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[2] This section was added to the Act in 1972. Pub. L. No. 92-603, Section 243(a), 86 Stat. 1420.

[3] See 42 U.S.C. 1395*oo*(a); 42 C.F.R. 405.406(b) (1979).

a hearing before a Provider Reimbursement Review Board composed of five members appointed by the Secretary. The provider may obtain judicial review in district court of an adverse decision by the Board. 42 U.S.C. 1395*oo*(a) and (f). The Act contains no mechanism for judicial review of reimbursement determinations under Part A where the amount in controversy is less than $10,000.

The Act contains far more limited provisions for review of determinations made under Part B. Whether any benefits are payable under Part B of the Medicare Act for a particular service and the amount of such benefits are determined by the insurance carrier, not by the Secretary. 42 U.S.C. 1395u(a). The only provision for review of the carrier's determination is contained in 42 U.S.C. 1395u(b)(3)(C), which states that the Secretary's contract with the carrier must provide that an individual enrolled under Part B will have "an opportunity for a fair hearing by the carrier, in any case where the amount in controversy is $100 or more * * *." In contrast to benefit amount determinations under Part A, the Act does not provide for the Secretary or an appeals board to review benefit amount determinations by a carrier under Part B or grant the individual beneficiary a right of judicial review of such determinations. A physician or other person who furnishes supplies or services to an individual insured under Part B and accepts an assignment from that individual has the same right of review, including a hearing by the carrier, as the individual. 42 C.F.R. 405.801(a). But the Act does not grant the physician or other supplier under Part B an independent right to have the carrier's determination reviewed by the Secretary or a court. Compare 42 U.S.C. 1395*oo*.

Finally, by virtue of 42 U.S.C. 1395ii, the provisions of Section 205(h) of the Social Security Act, 42 U.S.C. 405(h), precluding review of findings and decisions by the Secretary except as provided in the Social Security Act itself (see page 3, *supra*), are expressly made applicable to the Medicare Act.

2. Respondent Erika, Inc. is a distributor of medical supplies used by patients undergoing kidney maintenance dialysis. Its customers include a large number of beneficiaries under Part B of the Medicare program. The Prudential Insurance Company was designated by the Secretary as the insurance carrier for the processing of Part B claims in New Jersey, where respondent's business is based. As the carrier, Prudential was responsible for determining the "reasonable charge" for supplies furnished by respondent to Part B beneficiaries, 42 U.S.C. 1395u(a)(1)(A), 80% of which would then be paid by the Medicare program, 42 U.S.C. (& Supp. III) 1395*l*. In determining the "reasonable charge" for Part B services, the carrier must take into account both the customary charge generally made by the particular person who furnished the Part B services and the prevailing charge made by all persons in the particular locality for similar services. 42 U.S.C. (& Supp. III) 1935u(b)(3). For each year involved in this lawsuit, a supplier's "reasonable charge" could not exceed the prevailing charge level that the carrier determined would cover 75% of all customary charges made for similar services in that locality during the calendar year preceding the 12-month period (beginning July 1 of each year) in which the bill was submitted. *Ibid.*[4]

Respondent's prices, which applied to both Medicare and non-Medicare sales, were listed in an annual catalogue effective July 1 of each year and in catalogue supplements issued during the succeeding twelve months to reflect price changes. Because respondent's sales accounted for almost all of the sales of the relevant supplies in the locality, Prudential utilized respondent's sales price for a particular product to fix the prevailing charge level that respondent's "reasonable charge" for that product could not exceed. As a result, the "reason-

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[4] This provision was amended in December 1980 by Section 946 of Pub. L. No. 96-499, 94 Stat. 2642.

able charges" for respondent's supplies in the 12-month period beginning July 1, 1975, were those listed in its July 1974 catalogue. Prudential did not increase respondent's "reasonable charges" to take into account intervening price increases.

When respondent sold its dialysis supplies to Part B beneficiaries, it received assignments of claims from the beneficiaries and submitted invoices to Prudential based on the prices in effect at the time of sale. Prudential reimbursed respondent, however, on the basis of the catalogue prices in effect on July 1 of the preceding calendar year. Respondent alleged (Supp. Pet. ¶ 45; see also *id.* at ¶¶ 29, 65) that it did not discover that Prudential had been making payments based on respondent's July 1, 1974 catalogue prices until early 1976. Respondent then requested that Prudential adjust the amounts of past and future payments to reflect intervening price increases. Pursuant to Section 5010.2 of HHS's Carriers Manual (App. F, *infra*, 69a), which allows for adjustments in the amount of customary charges in highly unusual situations where equity clearly warrants, Prudential made an adjustment, effective May 26, 1976, for sales of the drug heparin. But Prudential declined to make a retroactive adjustment for past sales of that drug, concluding that it had no authority to do so (App. A, *infra*, 5a-6a). For the other products involved in this case, Prudential declined to make any of the requested adjustments. Prudential's initial determinations were affirmed following the "fair hearing by the carrier" required by 42 U.S.C. 1395u(b)(3)(C).

3.a. Following the decision by Prudential's hearing officer, respondent filed this lawsuit in the Court of Claims, contending that Prudential's action was inconsistent with the Medicare Act, violated the due process and equal protection guarantees of the Fifth Amendment, and resulted in a taking of its property.

On cross-motions for summary judgment, the Court of Claims rejected the government's argument that the court lacked jurisdiction to decide respondent's reimbursement

claims. The Court of Claims held (App. A, *infra*, 6a-7a) that, on its face, respondent's contention that Prudential's refusal to account for its interim price increases violated the Fifth Amendment, the Social Security Act, and implementing regulations fell within the court's jurisdiction under the Tucker Act, 28 U.S.C. 1491. Moreover, the court rejected the argument that a congressional intent not to subject a carrier's Part B benefit determinations to judicial review was demonstrated by the fact that, in 42 U.S.C. 1395ff, Congress had expressly provided the individual beneficiary with a right of judicial review of his eligibility for and the amount of benefits under Part A, but had limited the right of judicial review under Part B to questions of the individual's eligibility for benefits. The court interpreted 42 U.S.C. 1395ff as establishing only the particular procedures to be utilized in obtaining judicial review, not as limiting the availability of such review (App. A, *infra*, 10a-11a, quoting *Whitecliff, Inc.* v. *United States*, 536 F.2d 347, 351 (Ct. Cl. 1976), cert. denied, 430 U.S.C. 969 (1977)):

> Where the Medicare statute provides for review, providers and courts must follow the specified procedures and limitations; in other cases, a provider may obtain judicial review, under the general jurisdictional provisions which are applicable, at least so far as to ensure compliance with statutory and constitutional guidelines.

In the court's view (App. A, *infra*, 11a), 28 U.S.C. 1491 is such a general jurisdictional provision for judicial review in the Court of Claims.

The court declined to attach significance to a passage in the Senate Report stating that the Act "does not provide for judicial review of a determination concerning the amount of benefits under Part B where claims will probably be for substantially smaller amounts than under Part A" (S. Rep. No. 404, 89th Cong., 1st Sess. 54-55 (1965)) and a similar statement made during floor con-

sideration of the 1972 amendments to 42 U.S.C. 1395ff that "[t]he situations in which medicare decisions are appealable to the courts were intended in the original law to be greatly restricted in order to avoid overloading the courts with quite minor matters" (118 Cong. Rec. 33992 (1972)). The court acknowledged that these statements reflected an intent to bar claims challenging the amount of reimbursement allowed in particular instances—"as, for example, a carrier's determination that $50 rather than the $100 a physician charged was a reasonable amount for the services" (App. A, *infra*, 14a). But this purpose to bar a flood of small claims would not be thwarted, the court reasoned, "by permitting judicial review of contentions that particular benefit determinations violated constitutional or statutory provisions. For once a particular contention of that kind had been adjudicated, that issue would be settled, and there would be no occasion for further litigation of the point" (*id.* at 14a-15a). Accordingly, the court did not find the statements in the legislative history to be "clear and convincing" evidence of a congressional intent to preclude judicial review of Part B determinations (*id.* at 14a).

b. On the merits, the Court of Claims found that Prudential had violated the requirement in 42 U.S.C. (& Supp. III) 1395u(b)(3) that the prevailing charge level for the 12-month period beginning July 1 of each year be calculated on the basis of charges in the locality "*during* the last preceding calendar year" (App. A, *infra*, 15a-16a) (emphasis added) by looking to the respondent's catalogue charges in effect on July 1 of that year. According to the court, Prudential was required to take into account prices charged before July 1, which may have been lower than the catalogue price, as well as any price increases effective later in the calendar year. The court therefore remanded the case to Prudential to redetermine respondent's reasonable charges in accordance with its opinion, using such method of cal-

culation as Prudential in its discretion deemed appropriate (App. A, *infra*, 22a).[5]

With respect to the drug heparin, the court determined (App. A, *infra*, 19a-21a) that Prudential's hearing officer had erred in relying solely upon a particular HHS directive in deciding that it could not make a retroactive adjustment in the charges allowed because, in the court's view, that directive had become obsolete. It therefore remanded this aspect of the case to Prudential as well to determine whether a retroactive adjustment should or could be made under whatever other standards and policies the Secretary had promulgated.[6]

Finally, the court found "insubstantial" respondent's claim that Prudential's failure to reimburse it on the basis of its current charges, rather than prevailing charge levels in the preceding calendar year, denied it due process and equal protection (App. A, *infra*, 22a). The court found it reasonable for Congress, "in order to control Medicare costs and to provide an orderly system for administering this vast and complex program, to base reim-

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[5] Respondent did not challenge Prudential's determination on this ground in its "fair hearing" conducted by Prudential or in the Court of Claims, perhaps because Section 5010.1 of the Carriers Manual (App. G, *infra*, 89a-90a) expressly allows a carrier to utilize a price list in effect at the midpoint of the calendar year in calculating a supplier's customary charges if the carrier does not have adequate statistics on prices charged by the supplier throughout the year. The court's order on the government's petition for rehearing (App. C, *infra*, 30a-33a) made clear that the validity of Section 5010.1 of the Carriers Manual had not been determined.

[6] The court rejected respondent's argument that Prudential should have adjusted respondent's "reasonable charges" for supplies other than heparin to take increased prices into account. The court observed (App. A, *infra*, 21a) that the determination whether to grant an adjustment and permit a departure from prevailing charges for the preceding calendar year "is within the discretion of the carrier," and it concluded that it could not "direct Prudential whether or how to exercise that discretion in a particular case" (*ibid.*).

bursement on charges made during the prior year" (App. A, *infra*, 22a).

REASONS FOR GRANTING THE PETITION

The availability of judicial review of determinations under the Medicare Act is an important and recurring issue on which the lower courts have taken divergent positions and which warrants review by this Court. Review is especially appropriate in the instant case, because the Court of Claims has held that it is empowered to review individual benefit determinations by insurance carriers under Part B of the Act. The text and legislative history make clear that Congress deliberately foreclosed judicial review of such determinations, which typically involve relatively small amounts of money.

1. The Court of Claims' assumption of jurisdiction under 28 U.S.C. (& Supp. III) 1491 to review determinations by insurance carriers of the amount of benefits payable for a particular service under Part B of the Medicare Act is inconsistent with Congress' clearly expressed intention to preclude judicial review of those very determinations. As the Court of Claims recognized (App. A, *infra*, 19a), respondent's right to obtain reimbursement from Prudential for its sales of equipment and supplies to Part B beneficiaries derives solely from the beneficiaries' assignment to respondent of their individual reimbursement claims. Accordingly, respondent, as assignee of thousands of separate claims under Part B, may exercise only those rights of review enjoyed by the individual beneficiaries under the Act. 42 C.F.R. 405.801(a); *Szekely* v. *Florida Medical Ass'n*, 517 F.2d 345 (5th Cir. 1975), cert denied, 425 U.S. 960 (1976).

As explained above, 42 U.S.C. 1395ff provides an individual beneficiary with a right to a hearing before the Secretary and subsequent judicial review only with respect to the Secretary's determination of his *eligibility* for Part B benefits. The Act assigns the responsibility for making decisions on the *amount* of benefits payable for

a particular service under Part B not to the Secretary, but to insurance carriers that are experienced in determining reasonable and customary charges for medical services in the particular locality by virtue of their insurance business in the private sector. S. Rep. No. 404, 89th Cong., 1st Sess. 53-54 (1965); H.R. Rep. No. 213, 89th Cong., 1st Sess. 46 (1965). Where the beneficiary wishes to dispute the carrier's initial benefit determination, the Act requires only that he be given "an opportunity for a fair hearing *by the carrier*" (42 U.S.C. 1395u(b)(3)(C); emphasis added). The statute makes no provision for a hearing by the Secretary or subsequent judicial review. Because, with respect to Part A benefit determinations, Congress *expressly* provided for a hearing by the Secretary where the amount in controversy is at least $100 and a right of judicial review where the amount in controversy is at least $1,000, 42 U.S.C. 1395ff(b)(2), traditional principles of statutory construction compel the conclusion that Congress' omission of comparable procedures under Part B was deliberate. *Fedorenko* v. *United States*, No. 79-5602 (Jan. 21, 1981), slip op. 20-21.

The legislative history of the Medicare Act confirms that Congress intended to preclude judicial review of benefit determinations under Part B. The Senate Report on the 1965 Act states:

> Hearings and judicial review are * * * provided for where an individual is dissatisfied with a determination as to the amount of benefits under the hospital insurance plan if the amount in controversy is $1,000 or more. (*Under the supplementary plan, carriers, not the Secretary, would review beneficiary complaints regarding the amount of benefits, and the bill does not provide for judicial review of a determination concerning the amount of benefits under part B where claims will probably be for substantially smaller amounts than under part A.*) Hospitals, extended care facilities, and home health agencies would be entitled to hearing and judicial review if they are dissatisfied with the Secretary's determination

> regarding their eligibility to participate in the program. *It is intended that the remedies provided by these review procedures shall be exclusive.*

S. Rep. No. 404, *supra*, at 54-55 (emphasis added); see also H.R. Rep. No. 213, *supra*, at 47. Thus, as the last quoted sentence makes clear, the designated remedy for complaints regarding the *amount* of benefits under Part B—review by the carrier, not the Secretary, and without a right of judicial review—was plainly intended to be "exclusive."

This conclusion is evident as well from the incorporation into the Medicare Act, through 42 U.S.C. 1395ii, of Section 205(h) of the Social Security Act, 42 U.S.C. 405(h). The first two sentences of Section 205(h) provide (emphasis added):

> The findings and decisions of the Secretary after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Secretary shall be reviewed by any person, tribunal, or governmental agency except as herein provided.

Because the carrier acts on behalf of the Secretary in making benefit determinations (S. Rep. No. 404, *supra*, at 54), the carrier's findings and decision are binding upon the parties to the "fair hearing by the carrier" provided by 42 U.S.C. 1395u(b)(3)(C), and they cannot be reviewed "by any person, *tribunal* or governmental agency" (emphasis added), since nothing in the Act provides for such review. *Weinberger* v. *Salfi*, 422 U.S. 749, 757 (1975); *Califano* v. *Sanders*, 430 U.S. 99, 110-111 (1977) (Stewart, J., concurring in the judgment).

The congressional intent to preclude review of Part B claims was reiterated in 1972 when 42 U.S.C. 1395ff was revised in certain respects. The Conference Report stated:

> Amendment No. 561: The Senate amendment added a new section to the House bill which would

> make clear that *there is no authorization for an appeal to the Secretary or for judicial review on matters solely involving amounts of benefits under Part B*, and that insofar as Part A amounts are concerned, appeal is authorized only if the amount in controversy is $100 or more and judicial review only if the amount in controversy is $1,000 or more.
>
> The House recedes.

H.R. Conf. Rep. No. 92-1605, 92d Cong., 2d Sess. 61 (1972).[7] See also 118 Cong. Rec. 33992 (1972) (remarks of Sen. Bennett).

The Court of Claims' conclusion that it may review Prudential's determination of the amount of benefits payable on the thousands of individual Part B claims assigned to respondent is inconsistent with this congressional judgment. The court's holding threatens to intrude the Court of Claims into the carriers' day-to-day administration of the Medicare program and to open that court to the very flood of small claims Congress sought to foreclose. Compare *Johnson* v. *Robison*, 415 U.S. 361, 370-373 (1974). Statistics compiled by the Department of Health and Human Services disclose that during calendar year 1980, Part B carriers such as Prudential received 2,163,786 requests for informal review of their initial

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[7] As orginally enacted in 1965, 42 U.S.C. 1395ff(b) provided that a beneficiary had a right to a hearing by the Secretary on Part A benefit determinations where the amount in controversy was $100 or more and to judicial review where the amount in controversy was $1,000 or more (42 U.S.C. (1970 ed.) 1395ff), but did not expressly bar the right to a hearing and judicial review where the amount in controversy was less than these amounts. As amended in 1972, 42 U.S.C. 1395ff(b)(2) now states that a hearing by the Secretary and judicial review are *not* available under that section where the amount in controversy is less than the prescribed amounts. The text of the 1972 amendments does not expressly refer to benefit determinations under Part B, but the Conference Committee report quoted in the text leaves no doubt that Congress intended to bar judicial review of such determinations in all cases.

determinations. See 42 C.F.R. 405.807 *et seq.* The carriers affirmed their initial determinations in 975,143 of these cases. During the same period, carriers received 26,171 requests for "fair hearings," and their determinations were upheld after a hearing in 7191 cases. If only a fraction of the total number of disappointed claimants were to seek review in the Court of Claims, the cited statistics indicate that there would be a considerable increase in that court's docket. This would, in turn, strain the scarce resources of the Secretary in defending against relatively minor monetary claims.[8]

2. The decision below also is contrary to the decisions of this Court in *United States* v. *Mitchell*, 445 U.S. 535 (1980), and *United States* v. *Testan*, 424 U.S. 392 (1976), regarding the jurisdiction of the Court of Claims under 28 U.S.C. (& Supp. III) 1491. In those cases, the Court held

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[8] The Court of Claims attempted to limit its holding by indicating that it would accept any case where it is alleged that a carrier "may have substantially violated * * * the provisions of the governing statute" (App. A, *infra*, 9a, quoting *Goldstein* v. *United States*, 201 Ct. Cl. 888, cert. denied, 414 U.S. 974 (1973)), but that it would not review benefit amount determinations in individual cases (*id.* at 14a). This attempt to confine the jurisdictional holding fails for a number of reasons. First, the standard virtually defies precise application, thereby inviting litigation, not preventing it, as the Court of Claims appeared to believe (*id.* at 14a-15a). Second, under the suggested standard, claims for increased Part B benefits would appear to be reviewable in any case in which a beneficiary (or his assignee) alleges that (1) the Medicare Act requires increased reimbursement; (2) a regulation is inconsistent with or unauthorized by the statute; or (3) the amount of benefits determined is less than would have resulted if the statute or regulation had been properly applied. Any artful pleader could bring his case under one of these tests, at least for purposes of defending against a motion to dismiss. Third, and most fundamentally, the Court of Claims failed to appreciate that every claim that a carrier's Part B benefit determination is inconsistent with the statute or implementing regulations is a challenge to the *amount* of benefits actually awarded and therefore foreclosed by 42 U.S.C. 405(h) and the text and legislative history of 42 U.S.C. 1395ff.

that 28 U.S.C. 1491 is only a jurisdictional statute that "does not create any substantive right enforceable against the United States for money damages" and that individual claimants therefore must look elsewhere for a waiver of sovereign immunity to suit with respect to their claims. 445 U.S. at 538; 424 U.S. at 398. See also *United States* v. *Hopkins*, 427 U.S. 123, 130 (1976). To support respondent's statutory claims, then, it is necessary to find in the Medicare Act a substantive right to money damages for violations of the Act. The Court of Claims ignored that requirement in this case by concluding (App. A, *infra*, 6a-7a) that it had jurisdiction of respondent's statutory claims under 28 U.S.C. 1491 solely because respondent had alleged that Prudential's practices violated the Social Security Act.[9]

Moreover, the Court stressed in *Mitchell* and *Testan* that a waiver of sovereign immunity to suit in the particular statute relied upon " 'cannot be implied but must be unequivocally expressed' " (445 U.S. at 538; 424 U.S. at 399, both quoting *United States* v. *King*, 395 U.S. 1, 4 (1969)). There is no "unequivocally expressed" waiver of sovereign immunity to suit on individual claims to benefits under Part B of the Medicare Act. To the con-

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[9] Although the Court of Claims did not articulate its reasoning, the court may have believed that because the Medicare Act provides for the payment of benefits, it therefore " 'can fairly be interpreted as mandating compensation by the Federal Government' " (*United States* v. *Testan*, *supra*, 424 U.S. at 400, quoting *Eastport S.S. Corp.* v. *United States*, 372 F.2d 1002, 1009 (Ct. Cl. 1967)) whenever the statute is wrongly applied in the context of a particular benefit determination. See *Whitecliff, Inc.* v. *United States*, 536 F.2d 347, 351 (Ct. Cl. 1976), cert. denied, 430 U.S. 969 (1977). But the question under 28 U.S.C. 1491 is whether Congress has waived the United States' sovereign immunity to *suit* to recover the amounts owing as the result of an allegedly erroneous benefit determination, not whether it has waived an "immunity" to the payment of money. Thus, the mere fact that Congress has chosen to distribute monetary benefits administratively—or, here, through private insurance carriers—does not necessarily mean that Congress also intended to subject the United States to suits for damages for allegedly erroneous administrative decisions. Compare *Johnson* v. *Robison*, *supra*.

trary, the text and legislative history of the Medicare Act discussed above demonstrate that Congress deliberately withheld a right of judicial review of the amounts of benefits payable under Part B.

In addition, in the third sentence of Section 205(h) of the Social Security Act, 42 U.S.C. 405(h), as incorporated into the Medicare Act, Congress has expressly foreclosed the federal district courts from exercising their Tucker Act jurisdiction (28 U.S.C. (& Supp. III) 1346(a)(2)) to entertain actions against the United States to recover on any claim arising under the Medicare Act. It is most unlikely that when Congress enacted the Medicare Act and expressly declined to waive the government's sovereign immunity to suit in district court for a money judgment under the Tucker Act, it nevertheless implicitly waived its immunity to suit under the Tucker Act in the Court of Claims. That result would be especially anomalous with respect to Part B Medicare claims, which typically involve relatively small amounts of money and therefore are precisely the type of cases for which Congress has provided Tucker Act jurisdiction in the district courts.[10]

Finally, the manner in which the Court of Claims will exercise its jurisdiction in these cases demonstrates the error of its jurisdictional holding. The court stated that it would not review the amount of individual benefit determinations (App. A, *infra*, 14a). Rather, if the court finds a statutory error, as it did in this case, it will remand to the carrier for an exercise of its discretion applying appropriate legal standards. Thus, the court

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[10] Indeed, where Congress provided for judicial review under the Medicare Act, it mandated that the procedures in 42 U.S.C. 405(g) be followed, including the requirement that a petition for review be filed within 60 days of the Secretary's decision. In contrast, a claimant would presumably have six years to bring an action in the Court of Claims under the Tucker Act. 28 U.S.C. (& Supp. III) 2415. Congress could not have intended such a result. *Califano* v. *Sanders*, *supra*, 430 U.S. at 108.

will not award a judgment of "actual, presently due money damages" (*United States* v. *King*, *supra*, 395, U.S. at 3), but will, instead, grant a form of equitable relief by way of remand. This underscores the conclusion that the Court of Claims is not the proper forum in which to resolve these claims. *United States* v. *Testan*, *supra*, 424 U.S. at 404-405; J. Rogers, *A Way Out of the Social Security Jurisdiction Tangle*, 21 Ariz. L. Rev. 689, 719-721 (1979)[11]

3. The decision of the Court of Claims is inconsistent with the decisions of other federal courts regarding the availability of judicial review of benefit determinations under the Medicare Act. In this case, the Court of Claims held that 42 U.S.C. 1395ff merely establishes procedures for review of certain determinations under the Act but does not bar other avenues of judicial review where 42 U.S.C. 1395ff is inapplicable (App. A, *infra*, 9a-11a). This conclusion was drawn directly from the court's earlier decision in *Whitecliff, Inc.* v. *United States*, *supra*,[12] in which it refused to apply the preclusion of

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[11] The Court need not consider whether jurisdiction lies in some forum to consider constitutional challenges to the Medicare Act or the manner of its implementation because the Court of Claims found respondent's constitutional arguments in this case to be insubstantial (App. A, *infra*, 22a). In any event, the Fifth Amendment Due Process Clause (including its equal protection component), upon which respondent relied below, does not mandate the award of money damages for violations, and cases arising under that Clause therefore do not fall within the Court of Claims' jurisdiction under 28 U.S.C. 1491. See *Muehlen* v. *United States*, 209 Ct. Cl. 690 (1976).

[12] In *Whitecliff*, the Court of Claims held that it had jurisdiction under 28 U.S.C. 1491 to review a challenge by a provider of services under Part A of the Act of the determination by a fiscal intermediary of the amount of reimbursements to which the provider was entitled for the years 1967 to 1970. Although the Court denied the government's petition for certiorari in *Whitecliff*, we had informed the Court (Petition for a Writ of Certiorari (No. 76-1188, Oct. Term 1976) at 6, 9-10) that disputes of this type arising after 1973 were expressly made subject to judicial review under 42 U.S.C. 1395*oo*. Hence, the Court may have concluded that the

review provisions of 42 U.S.C. 405(h) to Medicare cases despite the incorporation of that section in the Medicare Act. See 536 F.2d at 350-351.

The Court of Claims' reading of 42 U.S.C. 405(h) not to bar even non-constitutional challenges to benefit determinations not expressly made reviewable under the Medicare Act itself conflicts with the conclusion reached by a number of courts of appeals. *See Kechijian* v. *Califano*, 621 F.2d 1 (1st Cir. 1980); *Bussey* v. *Harris*, 611 F.2d 1001, 1005 n.5 (5th Cir. 1980); *Drennan* v. *Harris*, 606 F.2d 846, 850 (9th Cir. 1979); *Trinity Memorial Hospital* v. *Associated Hospital Service, Inc.*, 570 F.2d 660, 666 (7th Cir. 1977); *St. Louis University* v. *Blue Cross Hospital Service*, 537 F.2d 283, 287-289 (8th Cir.), cert. denied, 429 U.S. 977 (1976).[13]

Several of these decisions make clear that there is no right of judicial review of a carrier's benefit determinations under Part B—the very determinations the Court of Claims found to be reviewable in this case. *Kechijian* v. *Califano, supra*, 621 F.2d at 3-4; *Bussey* v. *Harris, supra*, 611 F.2d at 1005 n.5; *Drennan* v. *Harris, supra*, 606 F.2d at 850 n.1; cf. *St. Louis University* v. *Blue Cross Hos-*

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question of jurisdiction over pre-1973 provider reimbursement disputes was not of sufficient continuing importance to warrant review. This same factor may explain the Court's denial of certiorari in *Dr. John T. MacDonald Foundation, Inc.* v. *Califano*, 571 F.2d 328 (5th Cir.), cert. denied, 439 U.S. 893 (1978), which likewise involved a pre-1973 provider dispute under Part A.

The reviewability of carrier benefit determinations under Part B, in contrast, is of substantial continuing importance, because Congress has not provided an alternative means of judicial review of such determinations. Indeed, Congress reiterated its intention to *foreclose* judicial review of such determinations under Part B in the same 1972 amendments in which it granted a limited right of judicial review of provider disputes under Part A.

[13] However, some courts of appeals have taken the position that, notwithstanding 42 U.S.C. 405(h), they have jurisdiction under 28 U.S.C. 1331 of constitutional challenges to administration of the Medicare program. *Chelsea Community Hospital* v. *Michigan Blue Cross Ass'n*, 630 F.2d 1131 (6th Cir. 1980); *St. Louis University* v. *Blue Cross Hospital Service, supra*, 537 F.2d at 291-293; see also *Kechijian* v. *Califano, supra*, 621 F.2d at 4.

pital Service, supra, 537 F.2d at 289, 293. Contrary to the Court of Claims, these courts have recognized that judicial review of Part B benefit determinations would "involve the court in the complex and detailed task of 'ascertaining the appropriate medical charges for technical services—based on facts which vary from community to community' " and that " 'the proper amount of these charges is peculiarly suited to determination by a specialized agency' " (*Kechijian* v. *Califano, supra*, 621 F.2d at 3, quoting *St. Louis University* v. *Blue Cross Hospital Service, supra*, 537 F.2d at 289).

The holdings of these courts mean little, however, if claimants challenging benefit determinations under Part B may bring suit in the Court of Claims. Hence, review by this Court is essential to resolve the uncertainty in the lower courts on the important and recurring jurisdictional question presented in this case.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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MARCH 1981

APPENDIX A

UNITED STATES COURT OF CLAIMS

No. 374-77

ERIKA, INC.

v.

THE UNITED STATES

Oct. 22, 1980

Stephen H. Oleskey, Boston, Mass., attorney of record, for plaintiff. Timothy H. Gailey and Hale & Dorr, Boston, Mass., of counsel.

Dwight D. Meier, Washington, D.C., with whom was Asst. Atty. Gen. Alice Daniel, Washington, D.C., for defendant. Margaret Porter, Dept. of Health and Human Services, Washington, D.C., of counsel.

Before FRIEDMAN, Chief Judge, and DAVIS, NICHOLS, KASHIWA, KUNZIG, BENNETT, and SMITH, Judges, en banc.

ON CROSS-MOTIONS FOR PARTIAL SUMMARY JUDGMENT

FRIEDMAN, Chief Judge:

This case, before us on cross-motions for partial summary judgment,[1] presents two questions under

[1] At the time the motions were filed, defendant informed the court that the parties were involved in settlement negotiations over count I of the three-count supplementary petition. Neither party has addressed the issues in that portion of the complaint. This opinion, therefore, addresses only the issues under counts II and III.

part B of the Medicare program (Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.* (1976)): (1) are any determinations relating to benefits under part B judicially reviewable, and (2) if the determinations here involved are reviewable, were the bases upon which they were made invalid because they are inconsistent with the statutory provisions governing those determinations? We answer both questions affirmatively. Accordingly, we grant the plaintiff's and deny the defendant's motions for partial summary judgment.

I.

A. The Medicare Program, which pays portions of certain medical expenses primarily for persons more than 65 years old, is divided into two parts. Part A is a hospital insurance program which covers all qualifying persons, and part B is a voluntary supplemental insurance program. Coverage under both parts of the program was extended on July 1, 1973, to any person, regardless of age, who requires kidney maintenance dialysis, and is otherwise covered by the Act. 42 U.S.C. § 426(e).

Part A of Medicare, *id.* §§ 1395c to 1395i-2, pays the costs of inpatient hospital services and extended care services. *Id.* §§ 1395c, 1395d. Patients receive the services without charge. Costs are paid out of the Federal Hospital Insurance Trust Fund, which is supported primarily by Social Security taxes. *Id.* § 1395i. Generally a hospital agrees to become a "provider of services" under the program and is reimbursed for its "reasonable costs" through a fiscal intermediary designated by the Secretary of Health,

Education, and Welfare. *Id.* §§ 1395f, 1395h.[2] If a provider is dissatisfied with the amount its intermediary awards, and if the amount in controversy is $10,000 or more, it may seek a hearing before the Provider Reimbursement Review Board. *Id.* § 1395*oo* (a). That Board's decision may be appealed to the Secretary. *Id.* § 1394*oo*(f).

Part B of Medicare, *id.* §§ 1395j-1395w, pays for the "reasonable charges" of physicians and various health services such as x-rays and laboratory tests. *Id.* §§ 1395*l*, 1395x(s). Individual participants pay premiums for coverage, which go into the Federal Supplementary Medical Insurance Trust Fund. *Id.* § 1395t. Part B benefits are administered by insurance carriers,[3] pursuant to contracts entered into with the Secretary. *Id.* § 1395u. The carriers set reasonable charges for 80 percent of which an individual, or a provider as assignee, may be reimbursed pursuant to guidelines set out in the Medicare statute and regulations. *Id.* The statute provides for "a fair hearing by the carrier" if a dispute arises over payment and the amount in controversy is $100 or more. *Id.* § 1395u(b)(3)(C). There is no provision for review of the carrier's decision by the Secretary or any governmental administrative agency.

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[2] In 1980 the name of the department was changed to Health and Human Services. Because the actions involved in this case predated that change, references are to the predecessor department.

[3] A carrier is an organization "lawfully engaged in providing, paying for, or reimbursing the cost of, health services under group insurance policies or contracts, medical or hospital service agreements, membership or subscription contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier." 42 U.S.C. § 1395u(f)(1).

B. Plaintiff (Erika) is a major distributor of equipment and supplies used in kidney dialysis. It sells to hospitals, health care facilities, and patients items it produces and items manufactured by others. The Prudential Insurance Company of America (Prudential) was designated as plaintiff's carrier, and therefore was authorized to "make determinations of the rates and amounts of payments required . . . to be made to providers of services . . . [on] a reasonable charge basis" (*id.* § 1395u(a)(1)(A)). Under the statute Prudential was to determine "reasonable charges" that were to be no greater than:

> the prevailing charge level that, on the basis of statistical data and methodology acceptable to the Secretary, would cover 75 percent of the customary charges made for similar services in the same locality during the last preceding calendar year elapsing prior to the start of the fiscal year in which the bill is submitted or the request for payment is made.

Id. § 1395u(b)(3).[4]

Because Erika's sales represented almost all the sales of the relevant materials in the locality where its business was based, Prudential used Erika's

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[4] In 1977 Congress amended this section by changing "the fiscal year" to "the twelve-month period (beginning July 1 of each year)," due to a change in the federal fiscal year. 42 U.S.C. § 1395u(b)(3) (Supp. I 1977). Prior to 1976 the government's fiscal year ran from July 1 to June 30. Beginning in 1976, however, the government's fiscal year began on October 1. Despite the change in language, the effect of the provision remains the same. The time period from July 1 to June 30 is now called "the fee screen year." Since all the claims in this case arose prior to 1977, the earlier language is applicable here.

charges to set the reasonable charges for dialysis equipment and supplies. It treated Erika's charges as both the customary charges for a seller and the prevailing charges for the locality. Erika's prices were listed in the company's annual catalogues, effective July 1 of each year. The company also issued from time to time catalogue supplements that reflected changes in price. Beginning with the July 1974 issue, plaintiff sent to Prudential its yearly catalogue and supplements.

Prudential determined Erika's "reasonable charges" for its fiscal years (which began on July 1)—and hence the basis for its reimbursement—by reference to Erika's charges set forth in its annual catalogue effective July 1 of the preceding year. The reasonable charges for the fiscal year beginning July 1, 1975, therefore, were those listed in the July 1974 catalogue, and the reasonable charges for the year beginning July 1, 1976, were those listed in the July 1975 catalogue. Prudential did not change those "reasonable charges" to reflect Erika's price increases shown in the company's catalogue supplements. Prudential reimbursed Erika for 80 percent of the reasonable charges it thus determined. *Id.* § 1395/(a)(1).

In this suit Erika challenges Prudential's refusal to increase Erika's "reasonable charges" to reflect its price increases made during the intervals between the effective dates of its annual catalogues. Count II of the complaint concerns charges for heparin, an anticlotting drug used in dialysis, from July 1974 through May 1976. The heparin Erika sold was manufactured by other firms. Plaintiff states that a shortage of meat from which the drug is produced caused a severe shortage of heparin beginning in 1974, that manufacturers of the drug raised their

prices to Erika, and that Erika increased its prices for heparin five times during this period to reflect its increased costs in obtaining the drug. Although Erika sent Prudential its supplements showing the increased prices, Prudential reimbursed Erika on the basis of the July 1, 1974 prices until May 26, 1976. It then approved Erika's charges for heparin reflected in Erika's March 1, 1976 supplement as the reasonable charges for future sales.

Prudential, however, refused to increase its prior reimbursements to reflect Erika's four earlier price increases, on the ground it had no authority to make such retroactive adjustments. After a hearing, the hearing officer (a Prudential employee) upheld the determination.

Count III seeks reimbursement to reflect the difference between the higher prices Erika actually charged for other equipment and supplies sold to Medicare beneficiaries (based upon the increases set forth in the supplemental catalogues) and the July 1 prices upon which Prudential based its payments. Despite periodic requests from Erika, Prudential refused to make any changes in Erika's "reasonable charges" to reflect those interim price changes. After a hearing, the hearing officer denied Erika any additional payments.

II.

The plaintiff invokes our jurisdiction under the Tucker Act, 28 U.S.C. § 1491, which gives us jurisdiction over "any claim against the United States founded either upon the Constitution, or any Act of Congress, or any regulation of an executive department." [5] The plaintiff contends that the refusal of

[5] The plaintiff also asserts we have jurisdiction under section 10(b) of the Administrative Procedure Act, 5 U.S.C. § 703. In view of our holding that we have jurisdiction under

Prudential to determine its "reasonable costs" under part B of Medicare to reflect the interim increases in Erika's charges above those contained in its annual catalogues violated the fifth amendment to the Constitution and the provisions of the Social Security Act and the implementing regulations governing the determination of "reasonable costs." On its face, the petition states a claim within our jurisdiction under the Tucker Act.

The defendant contends, however, that under 40 U.S.C. § 1395ff Congress made benefit determinations under part B of Medicare not judicially reviewable. That section provides:

> (a) Entitlement to and amount of benefits
>
> The determination of whether an individual is entitled to benefits under part A or part B, and the determination of the amount of benefits under part A, shall be made by the Secretary in accordance with regulations prescribed by him.
>
> (b) Appeal by individuals
>
> (1) Any individual dissatisfied with any determination under subsection (a) of this section as to—
>
> (A) whether he meets the conditions of section 426 or section 426a of this title, or
>
> (B) whether he is eligible to enroll and has enrolled pursuant to the provisions of part B of this subchapter, or section 1395i-2 of this title, or section 1819, or
>
> (C) the amount of benefits under part A (including a determination where such amount is determined to be zero)

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the Tucker Act, we find it unnecessary to consider this additional basis of jurisdiction. *But cf. Califano* v. *Sanders*, 430 U.S. 99, 97 S. Ct. 980, 51 L.Ed.2d 192 (1977).

shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title.

(2) Notwithstanding the provisions of subparagraph (C) of paragraph (1) of this subsection, a hearing shall not be available to an individual by reason of such subparagraph (C) if the amount in controversy is less than $100; nor shall judicial review be available to an individual by reason of such subparagraph (C) if the amount in controversy is less than $1,000.

(c) Appeal by institutions or agencies

Any institution or agency dissatisfied with any determination by the Secretary that it is not a provider of services, or with any determination described in section 1395cc(b)(2) of this title, shall be entitled to a hearing thereon by the Secretary (after reasonable notice and opportunity for hearing) to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title.

Section 405(g) of the Social Security Act permits any individual, after a final decision of the Secretary made after a hearing to which he was a party, to obtain review of the Secretary's decision by filing suit in the district court within 60 days. This provision would not permit Erika to obtain review of Prudential's denial of additional payment to it because that denial did not involve any "final decision" of the Secretary.

The government argues that under section 1395ff, the only issue upon which a hearing may be had before the Secretary under part B is whether an individual is entitled to benefits; and that there is no right to a hearing—and hence no right to judicial review—of a determination of the amount of benefits under part B, since the statute provides for a hearing on and judicial review of "amount" determinations only under part A. It contends that Erika's claim relates solely to the amount of benefits to which it is entitled and that section 1395ff therefore makes nonreviewable Prudential's refusal to pay Erika the additional amounts it seeks. The government argues further that the procedure provided in section 1395ff —a hearing before the Secretary and review in the district court—was intended to be the exclusive method for obtaining judicial review of Medicare determinations. In effect, the government argues that in section 1395ff Congress repealed by implication a portion of our jurisdiction under the Tucker Act.

We have rejected a similar contention by the government that section 1395ff and the provisions providing for district court review of determinations by the Secretary after a hearing bar us from reviewing decisions under part A of Medicare. In *Goldstein* v. *United States*, 201 Ct.Cl. 888, *cert. denied*, 414 U.S. 974, 94 S.Ct. 287, 38 L.Ed.2d 217 (1973), we held that with respect to the contention that a determination by a fiscal intermediary Provider Appeals Committee (1) "rested upon procedures which were constitutionally invalid or violative of the governing statute," or (2) "may have substantially violated the Due Process Clause of the Fifth Amendment or the provisions of the governing statute . . . the court has jurisdiction under 28 U.S.C. § 1491 and the finality

provisions of the medicare legislation do not bar judicial review." 201 Ct.Cl. at 889-90.

In *Whitecliff, Inc.* v. *United States*, 210 Ct.Cl. 53, 536 F.2d 347 (1976) *cert. denied*, 430 U.S. 969, 97 S.Ct. 1652, 52 L.Ed.2d 361 (1977), we held that we had jurisdiction under the Tucker Act to review the contention that the decision of a Provider Appeals Committee denying a Medicare part A provider's claim to certain payments violated the Medicare statute. 210 Ct.Cl. at 58, 536 F.2d at 351. We stated that reading the Medicare provision there involved[6] to preclude judicial review would "prevent all review of very large categories of cases and issues, including constitutional questions, and . . . accord absolute finality to adjudications by private organizations . . . Such a result would be of doubtful constitutional validity and would undermine the normal presumption in favor of judicial review." *Id.*, 536 F.2d at 350 (footnote omitted). We announced the following standard for judicial review of Medicare provider disputes:

> Where the Medicare statute provides for review, providers and courts must follow the specified procedures and limitations; in other cases, a provider may obtain judicial review, under the general jurisdictional provisions which are appli-

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[6] The provision in question was § 405(h) of the Social Security Act, made applicable to Medicare through § 1395ii. It limited review of a determination by the Secretary under the Act to that provided in § 405(g). *Weinberger* v. *Salfi*, 422 U.S. 749, 95 S.Ct. 2457, 45 L.Ed.2d 522 (1975). The government claimed in *Whitecliff* that § 405(h) also barred review of Medicare cases in this court. The court, however, refused to extend *Salfi* to such cases. 210 Ct.Cl. at 57-58, 536 F.2d at 350-51.

> cable, at least so far as to ensure compliance with statutory and constitutional provisions. In this court, 28 U.S.C. § 1491 (the Tucker Act) is the pertinent jurisdictional provisions both because of plaintiff's contract with the Government and also because the Medicare legislation, fairly read, mandates appropriate payment to providers.

Id., 563 F.2d at 351 (footnote and citation omitted). Although *Goldstein* and *Whitecliff* involved the reviewability of benefit determinations under part A, their reasoning is no less applicable to benefit determinations under part B. Indeed, our rulings in those cases did not specifically focus upon either part A or part B, but, more broadly, were that we have jurisdiction under the Tucker Act to review Medicare determinations challenged as violating constitutional or statutory provisions. Here the plaintiff contends that there has not been "compliance with statutory and constitutional provisions" (*Whitecliff*, *supra*, 210 Ct.Cl. at 58, 536 F.2d at 350) by Prudential in determinating Erika's benefits. Our conclusion in *Whitecliff* that the mere lack of explicit provisions for judicial review does not bar consideration of those Medicare claims under the Tucker Act is equally sound when applied here.

The Supreme Court has recognized that even an explicit provision barring judicial review does not necessarily do so in all cases. Section 211(a) of title 38 makes decisions of the Veterans' Administrator "final and conclusive" and provides that "no . . . court of the United States shall have power or jurisdiction to review any such decision by an action in the nature of mandamus or otherwise." Despite this sweeping language, the Supreme Court held in

Johnson v. *Robinson*, 415 U.S. 361, 94 S.Ct. 1160, 39 L.Ed.2d 389 (1974), that the federal courts could entertain a constitutional challenge to the Administrator's refusal to provide veterans' educational benefits to a conscientious objector who performed civilian service in lieu of military service. Noting that section 211(a) did not explicitly bar judicial consideration of Robinson's constitutional claims (*id.* at 367, 94 S.Ct. at 1165), the Court concluded that "neither the text nor the scant legislative history of § 211(a) provides the 'clear and convincing' evidence of congressional intent required by this Court before a statute will be construed to restrict access to judicial review. *See Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 141, 87 S.Ct. 1507, 1511, 18 L.Ed.2d 681 (1967)." *Id.* 415 U.S. at 373-74, 94 S.Ct. at 1168-1169.

Similarly, we have recognized that although the Civil Service Retirement Act provided that the decisions of the Civil Service Commission on questions of disability and dependency "are final and conclusive and are not subject to review," a court might set aside a Commission determination "where there has been a substantial departure from important procedural rights, a misconstruction of the governing legislation, or some like error 'going to the heart of the administrative determination.'" *Scroggins* v. *United States*, 184 Ct. Cl. 530, 533-34, 397 F.2d 295, 297, *cert. denied*, 393 U.S. 952, 89 S.Ct. 376, 21 L.Ed.2d 363 (1968), quoting *Gaines* v. *United States*, 158 Ct.Cl. 497, 502, *cert. denied*, 371 U.S. 936, 83 S.Ct. 309, 9 L.Ed.2d 271 (1962). *See also Polos* v. *United States*, Ct.Cl., 621 F.2d 385 at 391 n.9 (1980).

If, as those cases hold, the courts may entertain constitutional and statutory challenges to administrative action even where the governing statute explic-

itly bars judicial review, *a fortiori* the courts may do so where, as here, the alleged bar to judicial review is merely implicit in the statutory language and structure.

The government contends, however, that the legislative history of section 1395ff evidences a clear congressional intent to bar judicial review of any benefit determinations under part B of Medicare. It refers to the following statement in the Senate Committee Report on the Medicare bill:

> Under the supplementary plan [part B], carriers, not the Secretary, would review beneficiary complaints regarding the amount of benefits, and the bill does not provide for judicial review of a determination concerning the amount of benefits under part B where claims will probably be for substantially smaller amounts than under part A.

S.Rep.No.404, 89th Cong., 1st Sess. 54-55, *reprinted in* [1965] U.S.Code Cong. & Ad. News, pp. 1943, 1995. The governing also cites the following statement by Senator Bennett made during Senate debate on a 1972 amendment that changed the language of section 1395ff(b):

> The situations in which medicare decisions are appealable to the courts were intended in the original law to be greatly restricted in order to avoid overloading the courts with quite minor matters. The law refers to "entitlement" as being an issue subject to court review and the word was intended to mean eligibility to any benefits of medicare but not to decisions on a claim for payment for a given service.

118 Cong.Rec. 33,992 (1972).

These statements do not constitute "clear and convincing" evidence (*Johnson, supra*, 415 U.S. at 373, 94 S.Ct. at 1168) the Congress intended to bar judicial review of constitutional and statutory challenges to benefit determinations under part B of Medicare. The fair import of these statements is that Congress intended to bar judicial review of the amount of a particular benefit determination—as, for example, a carrier's determination that $50 rather than the $100 a physician charged was a reasonable amount for the services. Indeed, this court implicitly so ruled in *Goldstein, supra*, when it stated that "it is precluded by 42 U.S.C. § 1295ff and § 405(h) from reviewing or overturning the determination of the Provider Appeals Committee *except* insofar as such determination" rests upon constitutional or statutory error. 201 Ct.Cl. at 889 (emphasis supplied).

What this legislative history indicates is that Congress wanted to avoid flooding the courts with a large number of small claims in which beneficiaries challenged the amount of reimbursement allowed for a particular service or product. *Cf. Johnson, supra*, 415 U.S. at 370-72, 94 St.Ct. at 1167-1168. That this was the primary purpose of Congress in the provision is confirmed by the fact that under part A of Medicare Congress barred judicial review of the Secretary's determination if the amount in controversy is less than $1,000.

The congressional objective to prevent the courts from being burdened with a large number of small individual claims seeking greater reimbursement would not be thwarted by permitting judicial review of contentions that particular benefit determinations violated constitutional or statutory provisions. For once a particular contention of that kind had been

adjudicated, that issue would be settled, and there would be no occasion for further litigation of the point. *Cf. Johnson, supra*, 415 U.S. at 373, 94 S.Ct. at 1168.

III.

A. In one significant respect the basis upon which Prudential determined Erika's "reasonable charges" did not comply with the Medicare statute and the implementing regulations.

As noted in section I.A. above, the statute provides that a reasonable charge (referred to as the "prevailing charge" in the statute) cannot exceed 75 percent of the customary charge for similar services in the locality "during the last preceding calendar year elapsing prior to the start of the fiscal year in which the bill is submitted or the request for payment is made." 42 U.S.C. § 1395u(b)(3). The Secretary's regulations similarly provide for a maximum reasonable (prevailing) charge of not more than 75 percent of the customary charge "during the calendar year preceding the start of the fiscal year in which the claim is submitted or the request for payment is made." 20 C.F.R. § 405.504(a)(2)(i) (1976).[7] The touchstone for determining reasonable charges under both the statute and the regulations is the customary charge "during the calendar year" preceding the fiscal year for which reimbursement is sought.

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[7] References to the regulation are to the 1976 Code of Federal Regulations unless otherwise indicated. In 1977 the entire chapter involved here was moved to become chapter IV of title 42 concerning Public Health, without major changes. Subsequent to 1976, however, when the federal fiscal year was changed, the regulation, like the statute, was altered. 42 F.R.D. § 405.504(a)(2)(i) (1979). *See* note 4, *supra*.

In the present case Prudential treated Erika's charges as the customary charges (and the prevailing charges) for the service in the locality. Prudential, however, did not base its determination of Erika's "reasonable charges" upon Erika's customary charges "during" the preceding calendar year. Instead, it looked only to Erika's charges on July 1, the first day of Erika's fiscal year. In so doing, Prudential ignored the statutory directive, repeated in the regulation, that it was to make its determination of Erika's charges for the current fiscal year on the basis of those charges during the preceding calendar year. The statute and regulations did not permit Prudential to consider only Erika's charges on a single day in the middle of the preceding calendar year.

If Erika's charges had remained the same during the entire preceding calendar year, Prudential's error would have been immaterial. Erika, however, increased its charges during the preceding calendar year. Prudential's method of determining Erika's "reasonable charges" did not reflect those increases.

Prudential's failure to comply with the statutory directive is shown by the carrier's determination of Erika's "reasonable charges" for the drug heparin. For the fiscal year beginning July 1, 1975 (except for the 35 days after March 26, 1976, when Prudential based its reimbursement of Erika's charges on the latter date), Prudential reimbursed Erika on the basis of Erika's July 1, 1974 charges. In September 1974, Erika increased its charges for heparin, but the "reasonable charges" Prudential allowed did not reflect that increase.

The statutory standard that Erika's "reasonable charges" be calculated on the basis of Erika's charges during the preceding calendar year required Pruden-

tial's determination to reflect all price changes the provider made during that entire year. With respect to Erika's "reasonable charges" for heparin for the fiscal year 1975-76, this meant that Prudential's determination had to reflect the September 1974 price increase. Conversely, if during the first 6 months of 1974 Erika's charge for heparin was lower than its charge on July 1 of that year, Prudential should have taken that fact into account.

On the present record, we cannot determine what Erika's customary charges were for its drugs and services for each of the calendar years involved. Nor do we attempt to prescribe the method by which the carrier should make that determination. Prudential might decide to average the different charges made during the calendar year, or to allocate the different charges on the basis of the time each was in effect, or to determine the mean charge, or to use some combination of these methods. Perhaps Prudential can devise a better method of calculation.

The selection of the appropriate method of calculation is for Prudential to determine in the first instance. The carrier has considerable discretion to adopt whatever method of calculation it concludes would most accurately measure and reflect Erika's customary charges during the preceding calendar year. Our point simply is that under the statute and regulations, Prudential cannot ignore the changes in Erika's prices during the preceding calendar year and base its determination solely upon Erika's catalogue prices as of July 1.

In determining Erika's reasonable charges and reimbursing the provider for 80 percent of that amount, Prudential is acting for the Secretary pursuant to delegated statutory authority and the Sec-

retary's regulation. Prudential is an "administrative or executive body" under 28 U.S.C. § 1491, to which we may "remand appropriate matters . . . with such direction as [we] may deem proper and just." *Cf. Weinreb* v. *United Medical Service, Inc.*, 392 F.Supp. 45, 46 (S.D.N.Y. 1975); *Kuenstler* v. *Occidental Life Insurance Co.*, 292 F.Supp. 532, 534-35 (C.D. Cal. 1968). We therefore shall remand the case to Prudential to redetermine Erika's reasonable charges in accordance with this opinion.

B. Erika contends, however, that its "reasonable charges" for which the statute provides reimbursement are the amounts actually billed to its customers rather than its charges during the preceding year, and that Prudential therefore was required to increase the amount of reimbursement whenever Erika itself increased its prices. As we have explained in section III.A., however, Congress has provided that the reasonable charge cannot exceed the prevailing charge of 75 percent of the customary charges during the preceding calendar year.

Erika also states that because all of its sales were made through its headquarters in New Jersey and its Medicare claims were processed by Prudential (the carrier serving New Jersey) rather than by carriers throughout the country where Erika's patients were located, Erika's customary charges became the prevailing charges in the locality, which Prudential then used to determine Erika's reasonable charges. Erika contends that if its patients had asserted their own claims for reimbursement, rather than assigning the claims to Erika, they would have received higher reimbursement from other carriers throughout the country than Erika received from Prudential.

Of course, there is no way of knowing the amounts other carriers would have allowed if Erika's patients rather than Erika had presented the claims for reimbursement. Erika's contention that the amounts of reimbursement the other carriers would have allowed would have been higher than Prudential's payments thus is wholly speculative.

An equally serious flaw in Erika's argument is that its predicament, if such it be, is of its own choosing. Erika, for reasons of its business convenience and advantage, decided to accept assignments of its patients' Medicare claims rather than to collect directly from the patients and let the latter seek reimbursement from Medicare carriers in their locality. Having made that election, Erika cannot now legitimately complain because Prudential treated the claims Erika presented as claims by Erika rather than claims by Erika's patients. Although Erika's right to assert those claims derived from the assignment of the claims by the patients, it was not unreasonable for Prudential to deal with the claims presented by Erika as Erika's claims.

C. With respect to the drug heparin, which Erika did not manufacture but merely resold, Erika increased its prices five times between the promulgation of its July 1, 1974 price catalogue and May 26, 1976. It made these price increases allegedly solely because of price increases imposed by Erika's suppliers. On the latter date Prudential ruled that it would use Erika's then current higher price as a basis for future payments. Prudential, however, declined to give Erika any retroactive adjustment to reflect its past higher prices. It refused to make that retroactive adjustment either solely or primarily because of Intermediary letter 72-13, in which the Department of

Health, Education, and Welfare instructed carriers that adjustments in reimbursement payments on equitable grounds "may apply prospectively only." Erika contends that Prudential's reliance upon this letter was improper, and we agree.

As Prudential points out, Intermediary Letter 72-13 was issued in May 1972. It was designed to explain and to aid carriers in applying a Price Commission ruling concerning base prices for Medicare services during Phase II of the Wage and Price Control Program. It was in explaining the circumstances in which upward price adjustments could be made for equitable considerations that the letter stated that those adjustments "may apply prospectively only."

In terms, the letter applied only to adjustments for the fiscal year 1973. Moreover, as the hearing officer noted, Intermediary Letter 72-13 subsequently was declared to be "obsolete." The hearing officer concluded, however, that this latter action "does not necessarily negate its historical precedent." For this latter conclusion, the hearing officer relied upon two letters written by officials of the Department of Health, Education, and Welfare expressing their opinion that retroactive equity adjustments could not be made.

Prudential's reliance upon this letter, which did not cover the years in dispute here and which were declared "obsolete," was misplaced. Similarly, the two statements of the HEW officials which the hearing officer found convincing cannot be deemed to reflect the considered judgment of the Secretary. We therefore conclude that since Prudential's denial of a retroactive equitable adjustment rested either completely or primarily upon this Intermediary Letter, it cannot stand. Accordingly, we vacate that determination and remand this aspect of the case to Prudential

to reconsider its refusal to award retroactive benefits without reliance upon the Intermediary Letter or the two other opinions.

In so doing, we indicate no views on whether a retroactive adjustment should be made. That is a matter for Prudential to determine, in light of whatever governing standards and policies the Secretary has promulgated for retroactive adjustments.

D. In a period of rapidly rising costs and prices, such as the present, a provision requiring reimbursement upon the basis of charges during the prior calendar year may result in unfairness. It is Congress, however, which provided that standard for reimbursement under Medicare. If any change is to be made in that standard, it must come from Congress, not from this court.

The regulations give carriers substantial flexibility in setting reimbursement rates to look at more than just the customary and prevailing charges. In determining reasonable charges a carrier also may consider "[o]ther factors that may be found necessary and appropriate with respect to a specific item or service to use in judging whether the charge is inherently reasonable." 20 C.F.R. § 405.502(a)(4). Prudential apparently did consider Erika's special circumstances in connection with heparin when in May 1976 it granted Erika an increase that allowed the provider to be reimbursed at its current charges instead of its charges for the preceding calendar year. The determination whether to grant particular adjustments and permit departures from prevailing charges during the preceding calendar year, however, is within the discretion of the carrier. We cannot direct Prudential whether or how to exercise that discretion in a particular case.

E. Finally, Erika contends that Prudential's refusal to reimburse it on the basis of its current charges denied it due process and equal protection in violation of the fifth amendment to the Constitution. These constitutional claims are insubstantial. It was reasonable for Congress, in order to control Medicare costs and to provide an orderly system for administering this vast and complex program, to base reimbursement upon charges made during the prior year. Erika's participation in the Medicare program was voluntary. The limitations upon reimbursement that Erika here challenges did not deny Erika due process or equal protection. *See, e.g., Califano* v. *Aznavorian*, 439 U.S. 170, 99 S.Ct. 471, 58 L.Ed.2d 435 (1978); *Mathews* v. *Eldridge*, 424 U.S. 319, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976); *Dandridge* v. *Williams*, 397 U.S. 471, 90 S.Ct. 1153, 25 L.Ed.2d 491 (1970).

CONCLUSION

Plaintiff's motion for partial summary judgment is granted, and defendant's motion for partial summary judgment is denied. The case is remanded to the Prudential Insurance Company of America for further proceedings in accordance with this opinion.

NICHOLS, Judge, concurring:

I agree in the result and in the court's able opinion except as specified. I write separately on jurisdiction because I continue to believe that a practical necessity exists to advert to the doctrine of strict construction of the consent to be sued whenever we allow a claim that is in any way a departure from our usual routine. Since this is our first claim by a Medicare Part B provider, the instant case is novel in

that sense. Defendant is likely to abandon here any but *pro forma* insistence on jurisdictional objections when we have once established a precedent in favor of our own jurisdiction. Defendant before us does not waste time arguing issues we already have decided. Strict construction being jurisdictional, however, defendant always can invoke it in petitioning for certiorari without having said much or anything to alert us. We should, therefore, routinely show we have considered jurisdiction and have an answer, if we do, to all possible jurisdictional problems, whether or not urged before us by defendant.

When one considers the amazing changes that have occurred over a century of time in the meaning of the Constitution and laws, generally, as construed by the U.S. Supreme Court, the infrequency of its deviations from strict construction of the consent to be sued is almost anomalous. The doctrine is relatively firm when all else is in flux. It was already old when applied to the newly passed Tucker Act in *United States* v. *Jones*, 131 U.S. 1, 9 S.Ct. 669, 33 L.Ed. 90 (1889), and we have just now seen a litigant whose cause we favored stranded on it just as was claimant Jones. *United States* v. *Mitchell*, 445 U.S. 535, 100 S.Ct. 1349, 63 L.Ed.2d 607 (1980). It is true that Mr. Justice Holmes' colleagues allowed him to say for them, referring to the Tucker Act, in *United States* v. *Emery*, 237 U.S. 28, 32, 35 S.Ct. 499, 500, 59 L.Ed. 825 (1915):

> * * * [It is an] inadmissible premise that the great act of justice embodied in the jurisdiction of the Court of Claims is to be construed strictly and read with an adverse eye. * * * [Cases omitted].

Though the result of that case has stood, the language does not fairly and fully represent the policy of the Supreme Court then or now. Holmes himself in *United States* v. *Milliken Imprinting Co.*, 202 U.S. 168, 26 S.Ct. 572, 50 L.Ed. 980 (1906), thought he was being liberal to allow us to reform a contract and enforce it as reformed, though the Act then specifically granted equity jurisdiction. *Annell* v. *United States*, 384 U.S. 158, 86 S.Ct. 1384, 16 L.Ed.2d 445 (1966), is the only holding in conflict with the preponderance of cases. The quote proves only that nobody dared to edit Holmes' dicta. It, and the Lincoln quote that decorates our lobby, should never be reproduced without a qualifying reference to the doctrine of strict construction of the consent to be sued, and a tolling of the bell for all the litigants who have relied on such rhetoric in vain.

Among its other manifestations, the doctrine overturns the usual rule that repeals by implication are not favored. Partial repeals of the Tucker Act by implication are favored. Indeed, we ourselves recognized that such a partial repeal by implication did occur when we took jurisdiction of some Medicare Part A claims, but were careful to spell out, only those for which no district court remedy was provided, as the present opinion of this court correctly states in discussing *Whitecliff, Inc.* v. *United States*, 210 Ct. Cl. 53, 536 F.2d 347 (1976), *cert. denied*, 430 U.S. 969, 97 S.Ct. 1652, 52 L.Ed.2d 361 (1977). It is scarcely necessary to point out that in the absence of other provisions, all Medicare provider claims could have been sued on under 28 U.S.C. § 1491 (Tucker Act) nor that the provisions which reduced the number to less than all made no express reference to the Tucker Act and must, therefore, have

effected the partial repeal that did effect by implication only. And by inadvertence too, quite likely.

Congress is aware how easily it can effect a partial repeal of the Tucker Act by implication, and when it adverts to the problem and does not desire such partial repeal, it is careful to say so. A conspicuous long standing example is 28 U.S.C. § 1346(a). A more recent one is Pub.L.No. 92-562, Act of October 25, 1972, 86 Stat. 1176, codified 28 U.S.C. § 2409a. In *Fiorentino* v. *United States*, 221 Ct.Cl. ——, 607 F.2d 963 (1979), *cert. denied*, 444 U.S. 1083, 100 S.Ct. 1039, 62 L.Ed.2d 768 (1980) we discuss the effect of a partial implied repeal of the Tucker Act, there involved point out its involvement in *Brown* v. *GSA*, 425 U.S. 820, 96 S.Ct. 1961, 48 L.Ed.2d 402 (1976), and show that sovereign immunity (and the need of an express consent to be sued) greatly strengthens the probability that a partial repeal of the Tucker Act by implication has been effected in any class of case if the question arises.

There is, however, a big difference between an implied partial repeal of the Tucker Act in course of providing a seemingly adequate remedy elsewhere than in this court (actuated, perhaps, by a commendable desire to guarantee us an easy life with long vacations) and such an implied partial repeal in course of expressly denying relief elsewhere. Much will depend on the facts, but I do not think the Supreme Court has yet said or done anything to disable us from requiring defendant to show us express repeal of the Tucker Act in such circumstances. That is the effect of what we do here today. I deem it possible the momentum the Supreme Court has acquired on the strict construction issue may carry it to the length defendant's argument here would re-

quire, but I think we should let them get there first. It never does for a lower court to anticipate Supreme Court decisions. If anyone is to make such a flagrant and utter repudiation of the Holmes' *Emery* case rhetoric, it should be the Supreme Court, not ourselves. We can at least enjoy deeming ourselves to be in this area "the nation's conscience" until we are reversed, and the true straitness of the consent to be sued pointed out to us once again.

The difference is one that will appeal to most minds, but it is important not to overstress it. In our reasoning on consent to be sued issues, it is an error to be governed by the thought that the claimant must have a remedy here because he has none elsewhere. Our now reversed decision in *Mitchell* was infected by this fallacy. As I there pointed out, concurring, Congress has historically withheld its consent to be sued on many classes of claims over long periods, intentionally, preferring to handle itself the importunities of the claimants. The most that can be made of our *Mitchell* reasoning is that in some instances it will be a useful guide to legislative intent if otherwise unascertainable. It is helpful to ask sometimes whether a contemplated result is one the Congress would have wanted, if it had adverted to the problem. This reasoning cannot be used to clarify a consent to be sued, not stated in express terms, but perhaps it can if consent was once expressly granted and it is a later withdrawal of consent that is sought by defendant to be implied. In the instant case it is difficult to believe Congress would have wished to leave Erika, Inc. without a judicial remedy against the virtual spoliation revealed by the instand record, when such a remedy would have been unquestionable if Congress had just said nothing in its Social Security legislation about appeals and judicial review.

If a claimant can found a "colorable" claim on the Constitution, this may have an effect on the durability of an express consent to be sued against an implied withdrawal of it. *See Califano* v. *Sanders*, 430 U.S. 99, 109, 97 S.Ct. 980, 986, 51 L.Ed.2d 192 (1977). Acts of Congress relating to court jurisdiction and consent to be sued are to be construed in harmony with and not to thwart the purposes of the Constitution. *Russian Volunteer Fleet* v. *United States*, 282 U.S. 481, 491, 51 S.Ct. 229, 232, 75 L.Ed. 473 (1931). *Cf. Atkins* v. *United States*, 214 Ct.Cl. 186, 556 F.2d 1028 (1977), *cert. denied*, 434 U.S. 1009, 98 S.Ct. 718, 54 L.Ed.2d 751 (1978) (concurring opinion). I would consider Erika's constitutional claims to be "colorable," not "insubstantial" or "frivolous," but it is not necessary to decide if they are valid. A claim to a construction of a statute or regulation, strongly influenced by constitutional considerations, also must fall in the category of colorable constitutional claims. At any rate, in my view, defendant quite possibly was attempting to defend an unconstitutional result on jurisdictional grounds.

We have learned not to characterize a fifth amendment taking by what the taker chooses to call it. If the United States interposes between a manufacturer or dealer and his customers, leaving him no alternative but to sell his product to the government on the government's terms, that is a taking. The contrary argument or defense here is that Erika, Inc. could refuse to do any business with the United States, sell its kidney dialysis material to patients for cash only, and leave the patients to collect the government benefits when entitled. Whether this is valid depends on economic factors we would need evidence to resolve that we do not have. A trial to obtain it is not nec-

essary in the absence of indications that recovery on a fifth amendment theory would produce a larger award that what will ensure on the theory we espouse. Still, the constitutional theory is colorable, and being colorable, it aids our jurisdiction, which otherwise is probable but far from certain. The court therefore ought not to have given the theory the short shrift it has, and it should not have said Erika's participation in the program was "voluntary," which may be true and may be but a legal fiction. The voluntary nature of anyone's transactions with the government is not a simple matter to determine. Cf. *Sandnes' Sons, Inc.* v. *United States*, 199 Ct.Cl. 107, 462 F.2d 1388 (1972) where voluntariness was debated between majority and minority of this court sitting en banc. Erika may have, probably has, made its constitutional allegations mostly to aid our jurisdiction, and we should not spurn this aid.

APPENDIX B

IN THE UNITED STATES COURT OF CLAIMS

No. 374-77

ERIKA, INC.

v.

THE UNITED STATES

Filed Oct. 24, 1980

ORDER

This case comes before the court *sua sponte*, and on the basis of the remand as directed in the court's opinion of October 22, 1980.

IT IS FURTHER ORDERED that the case is removed from the court's docket and is no longer a pending case before this court.

BY THE COURT

/s/ Daniel M. Friedman
DANIEL M. FRIEDMAN
Chief Judge

Oct. 24, 1980

APPENDIX C

IN THE UNITED STATES COURT OF CLAIMS

No. 374-77

ERIKA, INC.

v.

THE UNITED STATES

Stephen H. Oleskey, attorney of record for plaintiff. *Timothy H. Gailey* and *Hale and Dorr*, of counsel.

Dwight D. Meier, with whom was *Assistant Attorney General Alice Daniel*, for defendant. *Margaret Porter*, Department of Health and Human Services, of counsel.

Before FRIEDMAN, *Chief Judge*, DAVIS, NICHOLS, KASHIWA, KUNZIG, BENNETT, and SMITH, *Judges, en banc.*

ON DEFENDANT'S MOTION FOR REHEARING

ORDER

The defendant has requested us to make clear that our opinion of October 22, 1980, was not intended to

invalidate a portion of section 5010.1 of the Medicare Carriers Manual.

In that opinion we held that in determining the plaintiff's reimbursable "reasonable charges" for Medicare services, The Prudential Insurance Company of America (Prudential), the plaintiff's insurance carrier, did not comply with the Medicare statute and the implementing regulations of the Secretary of Health, Education, and Welfare. The statute and regulations require that Medicare reimbursement be based upon the customary charge for such services in the locality where rendered during the "calendar year" "preceding" the year for which reimbursement was sought. Prudential based its determination of the plaintiff's reimbursement upon the plaintiff's charges on July 1, and refused to take account of the changes the plaintiff made in those charges, either before or after that date. We held that this was error because "[t]he statute and regulations did not permit Prudential to consider only Erik's charges on a single day in the middle of the preceding calendar year." Slip. op., p. 11.

Section 5010.1 of the Manual provides:

> When a carrier does not have adequate statistics on charges for suppliers of medical equipment, prosthetics, ambulance services, or for new services, the fees charged and the price lists in effect as of June 30 of that calendar year only should be used. The intent is to use a price list which can reasonably be assumed not to exceed the median of the prices charged by the supplier for his items and services during the calendar year.

In our decision we were not purporting to, and did not, determine the validity of that provision. All

we held was that "under the statute and regulations, Prudential cannot ignore the changes in Erika's prices during the preceding calendar year and base its determination solely upon Erika's catalogue prices as of July 1." Slip op., pp. 12-13.

More than a month-and-a-half after the government filed its motion for rehearing, the plaintiff filed a memorandum in opposition. In that memorandum the plaintiff stated that at a recent conference with defendant's counsel and representatives of the Social Security Administration and Prudential, the plaintiff's counsel was informed that because of the passage of time, Prudential no longer had the necessary data (which the plaintiff previously had supplied) to make the calculations required under our decision of October 22, 1980. The plaintiff states that it was informed that if the court grants the government's motion for rehearing, Prudential will assert

> that under the quoted language of section 5010.1 of the Medicare Carriers Manual it should be allowed on remand to use the single date catalogue approach which it was sued for using in the first place. It seeks, therefore, to evade completely the decision of this Court since such an action would result in Erika receiving no relief whatsoever for the improper actions of Prudential.

The clarification of our opinion that we are making in response to the defendant's motion for rehearing is intended solely to make clear that our decision implies nothing with respect to the validity or invalidity of the provision of section 5010.1 of the Manual quoted above. Prudential is required to carry out our mandate that on remand it conduct "further pro-

ceedings in accordance with this opinion." Prudential cannot now invoke section 5010.1 in an attempt to avoid compliance with our decision, on the basis of its claim that it no longer has the data that the plaintiff submitted to it.

BY THE COURT

/s/ Daniel M. Friedman
DANIEL M. FRIEDMAN
Chief Judge

Feb. 6, 1981

APPENDIX D

FORMAL HEARING PURSUANT TO TITLE XVIII, PART B, OF THE SOCIAL SECURITY ACT—("MEDICARE")

IN THE MATTER OF: ERIKA, INC., 560 Sylvan Avenue, Englewood Cliffs, NJ 07632, CLAIMANT

and

THE PRUDENTIAL INSURANCE COMPANY OF AMERICA, CARRIER

DETERMINATION OF HEARING OFFICER

Hearing held on February 11, 1977, at The Prudential Plaza Building in Newark, New Jersey.

Hearing Officer:

Henry A. Hartley

Appearances:

For the Claimant:

David T. Smith
Director—ERIKA, Inc.

Joseph E. Carson, Esquire
Attorney for ERIKA, Inc.

For the Carrier:

Robert W. Giordano
Associate Manager
Medical Administration Division

MATTER AT ISSUE:

Concerns the Claimant's request for retroactive equity increases for Heparin and CDAK #4 Hollow Fibre Kidney, which was denied by the Carrier. The Claimant has estimated the amount(s) at issue to be "in excess of $200,000 for both items".

HEARING TESTIMONY:

It was initially and mutually agreed by all parties present at the Hearing that the identical principle(s) and/or reasoning for the Carrier's denial of the Claimant's request for retroactive equity increases for Heparin and CDAK #4 Hollow Fibre Kidney was reasonably equally applicable. Although the separate files and/or exhibits for each item were individually reviewed and discussed, the testimony was primarily directed to the fact that the applicable Law, Regulations and Guidelines applied to both items.

Claimant succinctly described the CDAK #4 Hollow Fibre Kidney as a "catalog designation for a coil device . . . in the artificial kidney machine. It is a deletable part of the machine that is used and must be replaced on a regular basis". Heparin was described as "an anti-clotting agent . . . used for each dialysis treatment".

It was established that the Claimant discovered a printing error in their 1974 catalog for CDAK #4 and contacted the Carrier in February 1976, requesting an equity adjustment back to July, 1974. The price was listed at $246 whereas, the correct price was $294. The Carrier immediately agreed to the increased adjustment, but emphasized it could be on a prospective basis only. Approximately six months later, the Carrier received numerous forms from the Claimant, requesting recalculation of the previous al-

lowances. Claimant was again advised that equity increases or adjustments could be prospectively only. On May 18, 1976, the Claimant contacted the Carrier and advised that pursuant to the shortage of beef in November, 1974 . . . "and continuing to date" . . . resulting in the unavailability of raw materials needed to manufacture Heparin . . . "prompting absolutely astronomical increases in the market supply prices" . . . and requested and adjustment in the charge screen retroactively. The Carrier again advised the Claimant they could only grant an equity increase and/or adjustment prospectively.

Since the Carrier's decision to deny retroactive equity increases and/or adjustments were primarily premised on a provision in the Intermediary Letter 72-13 which provides: "Such adjustments may apply prospectively only"; the Claimant primarily challenged the Carrier's reasoning as follows:

(1) IL 72-13 was issued for explaining Phase II of the Economic Stabilization Program and applied exclusively to the fiscal year 1973. The phrase "prospective only" appears nowhere else in the manual, regulations or guidelines. Of significant importance, IL 72-13 has been "obsoleted" since the publication of Intermediary Letter Listing of July, 1974.

(2) IL 72-13 makes provision for retroactive correction—at least for CDAK #4. Part F, correctness of errors in charge screens, provides that errors in establishment or application of charge screens due to inaccurate data or other mistakes may be corrected during period of stabilization. Also, there is no similar prohibition on retroactive adjustment.

(3) The decision to deny retroactively is inconsistent with the established practice under the End-Stage Renal Program. The Bureau of Health Insurance

had allegedly made retroactive adjustments of estimated customary charges for kidney dialysis in circumstances not significantly different from the issues involved in this Hearing. Reference was made to a calculated adjustment made by BHI in 1975 in favor of the Queens (NY) Artificial Kidney Center.

APPLICABLE LAW, REGULATIONS, AND GUIDELINES:

On examination of specific parts of TITLE XVIII, Health Insurance for the Aged, and Public Law 89-97 of the Social Security Act, as amended, I find that the following sections of the Act, are relevant to this case:

> "*Section 1832 (a).* The benefits provided to an individual by the insurance program . . . shall consist of (1) entitlement to have payment made to him or on his behalf . . . for medical and other health services . . . ."
>
> "*Section 1833 (a).* . . . there shall be paid from the Federal Supplementary Medical Insurance Trust Fund . . . amounts equal to—(1) . . . 80 percent of the reasonable charges for the services . . . ."
>
> "*Section 1842 (a).* In order to provide for the administration of the benefits under this part, . . . the Secretary is authorized to enter into contracts with Carriers . . . which will . . . (1) (A) make determinations of the rates and amounts of payment required pursuant to this part to be made to providers of services . . . on a . . . reasonable charge basis. . . . (3) Each such contract shall provide that the Carrier . . . (B) will take such action as may be necessary

to assure that, where payment under this part for a service is on a charge basis, such charge will be reasonable. . . . (E) . . . there shall be taken into consideration the customary charges for similar services generally made by the physician or other person furnishing such services, as well as the prevailing charges in the locality for similar services."

"*Section 1871.* The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title. . . ."

The following Regulations of the Secretary of Health, Education and Welfare, promulgated for the administration of supplementary medical insurance program are applicable to this case:

"*405.502 Criteria for Determining Reasonable Charges—*

(a) Criteria—The law does not contemplate the establishment of a general fee schedule applicable to all physicians or other persons furnishing medical and other services but calls for individual determinations which take into account the facts as to existing practice with respect to charges of the particular physician or other persons as well as others in the locality. The two criteria set out in this law which are considered in determining reasonable charges are:

(1) The customary charges for similar services generally made by the physician . . .; and

(2) The prevailing charges in the locality for similar services.

* * * * *

(c) Application of Criteria—In applying these criteria, the Carriers are to exercise judgement [sic] based on factual data on the charges made by physicians to patients generally and by other persons to the public in general and on special factors that may exist in individual cases so that determinations of reasonable charge are realistic and equitable . . . ."

"*405.503 Determining Customary Charges.*—The term 'customary charge' will refer to the uniform amount which the individual physician or other person charges in the majority of cases for a specific medical procedure or service. . . .

* * * * *

(d) *Revision of customary charge.* . . . Where on the basis of adequate evidence, the Carrier finds that the physician or other person furnishing services has changed his charge for a service to the public in general, the customary charge resulting from the revised charge for the service should be recognized as the customary charge in making determinations of reasonable charges for such service when rendered *thereafter* to supplementary insurance beneficiaries. . ."

"*405.504 Determining Prevailing Charges.*—(a) Range of charges.—The term 'prevailing charges' refers to those charges which fall within the range of charges most frequently and most widely used in a locality for particular medical procedures or services. . . . Prevailing charges are derived from the overall pattern existing within a locality. . . . With respect to claims received by Carriers on or after January 1, 1971, no charge may be determined to be reasonable if

it exceeds the higher of (1) the prevailing charge limit that, on the basis of statistical data and methodology acceptable to the Secretary, would cover 75 per cent of the customary charges made for similar services in the same locality during the calendar year preceding the start of the fiscal year in which the determination is made, or (2) the prevailing charge limit in effect on December 31, 1970, provided such prevailing charge limit had been found acceptable by the Secretary."

"*405.860 Authority of the Hearing Officer*—The Hearing Officer in exercising the authority to conduct a Hearing under Section 1842 (b) (3) (C) of the Act is to comply with all the provisions of the Title XVIII of the Act and regulations issued thereunder, as well as policy statements, instructions and other guides issued by the Social Security Administration in accordance with the Secretary's agreement with the Carriers."

The following excerpts from DHEW Social Security Administration Intermediary Letters are applicable to this case:

"*Part B Intermediary Letter No. 70-10*—However, where a Carrier makes an adjustment in its customary charge screen under Exception 1 (will be permitted only in individually identified and highly unusual situations where equity clearly indicates the increases are warranted.), the Carrier may record a new fee as a customary charge after it has been made by the physician or other person to patients generally, for at least three months.—In each instance in which

a customary charge profile is changed under exception 1, the Carrier must fully document the situation and its determination, and have such documentation readily available for review by the Bureau of Health Insurance."

"*Part B Intermediary Letter No. 72-13*—Implementation of Price Commission's Phase II Reasonable Charge Policy—(a) Where it has come to the Carrier's attention that a 1971 charge reflects a price increase that was made contrary to Phase II guidelines or Phase II Regulations of the Price Commission, the charge may not be used in calculating customary charges.—As explained in the April 7 teletype, if the standard updating procedure referred to above were followed without modification, the charges allowed under the Medicare Program would rise approximately 6.2 percent in the aggregate during fiscal year 1973. Therefore, to limit the aggregate increase to 2.5 percent as required by the Price Commission, only 40 percent (2.5 is about 40 percent of 6.2) of the increases that would ordinarily have been allowed can be recognized.

2. Equity Adjustments in Customary Charges In addition to the scheduled updating of customary charges, other adjustments in customary charge limits may be made currently and through fiscal year 1973 in individually identified and highly unusual circumstances *where the equity considerations outlined in Enclosure I are met. Such adjustments may apply prospectively only.*

C. Carrier Responsibility for Monitoring Compliance with Phase II Limitations.

—However, where a Carrier becomes aware of fee increases that appear to violate these policies, it should promptly report them, together with such supporting information as may be available to the Carrier, to the District Director of Internal Revenue for the area in which the violation occurred."

The Department of Health, Education and Welfare of Social Security provided all Carriers with a Medicare Part B Carrier's Manual, as an aid in the processing of claims. I find the following Sections to be applicable to this case:

"*5010.2 Equity Adjustments in Customary Charge Screens.*—Once a Carrier has established the customary charge screens for a fiscal year, further increases (other than to correct errors) will be permitted only in individually identified and highly unusual situations where equity clearly indicates that the increases are warranted. Request for revisions in customary charge profiles should be initiated only by physicians or other persons furnishing covered services. Such requests should be neither encouraged nor discouraged by the Carrier, and each request will have to be handled on the basis of its own merits. All of the following considerations are to be taken into account, as applicable, in determining whether unusual circumstances warrant a revision in a customary charge profile in a particular situation:

A. *The time that has elapsed since the last change was made in the customary charge.*—

This involves finding out how long it has been since the last change, and if the physician or other person has had a change in his customary charge for the service in the past two or three years. Generally, the more time that has elapsed since the last change the stronger the case is for recognizing the current change.

Where the physician or other person states he did not increase his fees because of the government's request for restraint in this regard, and the Carrier can verify this through its claims records and/or information furnished by the physician or other person, it may take this factor into account in determining whether unusual circumstances are present in a particular case.

B. *The size of the requested increase and the relationship of the new and old charges to the charges made by others for the service.*—The Carrier should consider the amount of the requested increase and the relationship of the new and old charges to the customary charges of other physicians in the locality for the service.

C. *Increases in the physician's or other person's operating expenses which are used to justify an increase in charges.*—Where the physician or other person specifically makes the point and is able to establish that increases in his operating expenses are substantially above those resulting from general economic factors, and he substantially [sic] the uniqueness of his situation, the Carrier may consider this factor in determining whether an adjustment in its customary charge profile is warranted.

These are not the only factors that may be considered by the carriers in determining whether unusual circumstances exist to permit a re-evaluation of a physician's or other person's customary charge profile. They merely illustrate the kind of analysis a Carrier should make in deciding whether a customary charge profile should be adjusted. Such adjustments should be applied *prospectively only*, i.e., on claims processed after the date the Carrier determined the equity adjustment was merited.

Except in situations in which the regulations or BHI instructions provide specific exceptions, the amount recorded as a customary charge limit for a service in a Carrier's screen must normally be the median of the charges made by the physician or other person for the service during a full one-year period. However, where a Carrier makes an equity adjustment in its customary charge screen under this exception, the Carrier may record a new fee as a customary charge after the charge has been made by the physicians or other person to patients generally, for at least three months.

Generally, each Carrier has the responsibility for determining whether an equity adjustment in a physician's or other person's customary charge profile can be made. In each instance in which an adjustment is made, the Carrier must document the situation and its determination, and have such documentation readily available for review by the Bureau of Health Insurance. Normally, equity adjustments should be made in customary charge profiles only in a relatively small number of situations."

"*5010.3 Customary Charge Profile.*—Each Carrier should establish and maintain in readily usable form adequate data on the customary charges for specific services and procedures made by individual physicians and other persons and organizations which render covered services. Any method used (e.g., electronic data processing techniques or manual-clerical operations) to store data is acceptable so long as the results provide accurate and readily available information. The customary charge record for each physician or other person or organization rendering covered services should include at least (a) his name, office address, identification code, locality identification, and specialty status; (b) a continuing history of his charges for specific services, supplies etc., and (c) a customary charge for each specific service or item which has been derived from his history of charges for that service or item (and which is to be used as the basis for the determination of reasonable charges in conjunction with the prevailing charge criterion). The Carrier should develop and include in the profile for the physician or other person a customary charge conversion factor for use with a relative value scale where it does not have sufficient data to establish the actual customary charge, or where an infrequently performed procedure is involved.

Where the record contains a charge made under unusual circumstances, the record should, if possible, include a description of these circumstances. Such a charge should, however, not be used in calculating the physician's or other person's customary charge for a service in situations to which the unusual circumstances do not apply."

CONCLUSION AND DECISION:

The Claimant's principle thrust in their challenging arguments to the Carrier's refusal to grant equity increases and/or adjustments retroactively would appear to be the fact that Intermediary Letter 72-13, which they allege to be the Carrier's "sole basis" for refusing to act retroactively, has been "obsoleted" since the publication of Intermediary Letter Listing of July 1974.

And yet, on August 30, 1976, Mr. Joseph J. Czarnecki, the Resident Representative of the Bureau of Health Insurance with the Carrier, wrote the following opinion:

> "A customary charge screen is designed to represent a maximum allowable amount that is based on the *previous* charging practices of a physician or supplier. Several BHI issuances presume this understanding, sometimes without explicitly stating it (I.L. 70-10, the 12/17/68 letter to all contractors, etc.). Your reference to I.L. 72-13 is good. Moreover, regulations [sic] 405.503 (d) is just as explicit, stating that the revised customary charge will be used as the screen for services rendered *after* the revision has been made. A practical approach would permit use of the screen to claims received after the revision has been made."

Addenda thereto, on November 10, 1976, in response to a request from Mr. Leonard A. Estin, Executive Vice President of Erika, for a change in Medicare's current method of determining customary and prevailing charges for home dialysis supplies; Mr. Saverio DeRosa, Contractor Officer, of the Regional

Bureau of Health Insurance in New York City, wrote the following response:

> "Medicare Law specifies that Carrier prevailing charge screens for any July through June period may not exceed the 75th percentiles of customary charges for services in the preceding calendar year. The law specifically defines the base year from which charge data may be derived for the purpose of calculating reasonable charges. Once customary charge screens have been established for a year, further increases (other than to correct mathematical errors made in the calculation of prevailing charge amounts) are permitted only in individually identified and highly unusual situations where equity clearly indicates that increases are warranted. However, since the law sets forth the manner in which prevailing charges are to be calculated as precisely as it does, the equity adjustment provision is applicable only to customary charges. Current costs and currently charged prices for supplies cannot be considered by the Carrier in their prevailing charge calculations. Thus, under the established reimbursement criteria, established prevailing charge screens must stand, unless it can be determined that the Carrier improperly obtains base year charge data or committed mathematical errors in the calculation of prevailing charge amounts. Therefore, the Carrier has no authority to revise prevailing charges or base them on current year charges.
>
> Erika does have the right to file for an equity adjustment for its customary charges, but according to Medicare regulations, *even if an*

equity adjustment is granted there would be no retroactive adjustment as you suggest."

The Hearing Officer believes Intermediary Letter 72-13 established the Bureau of Health Insurance historical precedent concerning equity increases and/or adjustments on a prospective basis only. Although subsequently declared "obsolete" it does not necessarily negate its historical precedent, as substantiated by the 1976 written opinions of Messrs. Czarnecki and DeRosa, both officials with the Bureau of Health Insurance, and the October 1976 revision of Section 5010.3 of the Part B. Medicare Carriers Manual.

The Carriers responded expeditiously when the request(s) for equity increase(s) and/or adjustment(s) were received regarding both CDAK #4 and Heparin. The Hearing Officer finds no legitimate basis for retroactive equity increases and/or adjustments . . . or any Social Security Administration regulations or instructions, stated or implied, which would dictate retroactive payments in such a situation.

The Hearing Officer hereby concurs with the Carrier's decision to grant equity increase(s) and/or adjustment(s) prospectively regarding both CDAK #4 and Heparin, and to deny equity increase(s) and/or adjustment(s) retroactively.

In accordance with Section 405.835 of the Federal Regulations, this decision is binding on all parties to these claim(s) and Hearing.

This is the twelfth day of March 1977.

HENRY A. HARTLEY
Hearing Officer

LISTING OF EXHIBITS

ERIKA, INC.—MEDICARE PART B FAIR HEARING

HEPARIN Equity Increase:

Exhibit 1 Claimant letter, dated May 18, 1976, to the Carrier.

Exhibit 2 Carrier Intra-Office Memos, dated May 20-25, 1976.

Exhibit 3 Carrier Intra-Office Memo, dated May 26, 1976, re. clarification.

Exhibit 4 Claimant letter, dated June 1, 1976, to Carrier.

Exhibit 5 Claimant letter, dated June 10, 1976, to Carrier.

Exhibit 6 Carrier letter, dated July 26, 1976, to Claimant.

Exhibit 7 Carrier Office Memo, dated August 18, 1976, re. phone call from Joseph Casson, Attorney for Erika.

Exhibit 8 Carrier letter, dated August 24, 1976, to Joseph Casson—with copy to David Smith, Director, Erika, Inc.

Exhibit 9 Carrier Memo, dated August 24, 1976, to Mr. Czarnecki, Resident BHI.

Exhibit 10 Reply from Mr. Czarnecki, Resident BHI, to Carrier.

Exhibit 11 Claimant letter, dated September 3, 1976, to Carrier.

Exhibit 12 Letter, dated November 10, 1976, from Mr. DeRosa, Contractor Officer, BHI, to Mr. Estin, Erika Executive Vice President.

Exhibit 13 Hearing Officer's letter, dated January 3, 1977, to Claimant scheduling Hearing for January 11, 1977—which was subsequently changed to February 11, 1977.

CDAK #4 HOLLOW FIBRE KIDNEY—Retroactive Price Adjustment

Exhibit 1	Claimant letter, dated February 5, 1976, to Carrier.
Exhibit 2	Claimant letter, dated August 4, 1976, to Carrier.
Exhibit 3	Carrier letter, dated August 16, 1976, to Claimant.
Exhibit 4	Claimant letter, dated September 3, 1976, to Carrier.
Exhibit 5	Letter, dated November 10, 1976, from Mr. DeRosa, BHI, to Claimant.
Exhibit 6	Hearing Officer's letter, dated January 3, 1977, to Claimant.

The following Exhibits were submitted subsequent to the February 11, 1977 Hearing.

February 25, 1977	Three page brief, with attachments, from Joseph Casson, Attorney.
March 1, 1977	Two page rebuttal brief from R. W. Giordano, Medical Administration.

END OF LISTING.

APPENDIX E

May 9, 1977.

Arent, Fox, Klintner, Plotkin & Kahn
Counsellors at Law
Federal Bar Building
1815 H Street, N. W.
Washington, D. C. 20006

Att: Joseph E. Casson, Esquire

Re : ERIKA, INC.
Request to Reopen.

Dear Mr. Casson:

May this acknowledge receipt of your recent correspondence regarding the above-entitled matter.

I am quite certain you are aware that Appeals and Hearing procedures regarding Medicare claims are held in strict compliance with the directives of the Bureau of Health Insurance, Social Security Administration, and the Department of Health, Education and Welfare.

Federal Regulations #5, Sub-part B, Section 405.841, provides: "Reopening initial or review determination of the Carrier and decision of a Hearing Officer may be reopened by such Hearing Officer". This regulation is further amplified by Section 12100.2 of the Part B Medicare Carrier Manual (DHFA-SSA, 14-3) which provides: ". . . conditions under which a . . . decision may be reopened." Section 12100.7 provides: "Good cause may be considered for reopening." Section 12100.8 provides: "New and material evidence includes any evidence which was not considered when the previous determination was made

and which shows the facts that *may* result in a conclusion from that reached in the determination."

Section 405.835 provides: "The Hearing Officer's decision shall be final and binding on all parties to the Hearing unless it is revised in accordance with Section 405.841"—which I quoted in the above paragraph. In essence, the law does not provide for an appeal to the Social Security Administration from the Hearing Officer's decision . . . or for judicial review by Federal or State courts.

After very careful examination and review of the entire claim file, Hearing transcript, and your recent correspondence—with attachments, I do not find any "good cause in the form of new and material evidence" which was not considered when the previous determination(s) was made on March 12, 1977, and I hereby Affirm that original determination. This decision is binding on all parties to the claim(s) and Hearing.

Sincerely,

/s/ Henry A. Hartley
HENRY A. HARTLEY

APPENDIX F

FORMAL HEARING PURSUANT TO TITLE XVIII, PART B, OF THE SOCIAL SECURITY ACT—("MEDICARE")

HIC # Not Applicable

IN THE MATTER OF: ERIKA, INC., One Erika Plaza, Rockleigh, New Jersey 07647, CLAIMANT

and

THE PRUDENTIAL INSURANCE COMPANY OF AMERICA, CARRIER

DETERMINATION OF HEARING OFFICER

Hearing held on the 10th day of January, 1973 at The Prudential Insurance Company Plaza Building on Broad Street in Newark, New Jersey.

Hearing Officer:

Henry A. Hartley

Appearances:

For the Claimant:

Arent, Fox, Klintner, Plotkin
& Kahn, Esqs.
By: Joseph E. Carson, Esq.
Attorneys for the Claimant

David Thomas Smith
Comptroller for Claimant

For the Carrier:

Raymond Merola,
Senior Claim Advisor, Medical
Administration-Medicare

Betty Willis,
Supv. Claims Consultant, Medical
Administration-Medicare

Dennis DeMorat,
Assistant Claim Consultant,
Medical Administration-Medicare

MATTER AT ISSUE:

Concerns Medicare's reimbursement policies and an equity increase/adjustment(s) request by the Claimant for home dialysis kits and other dialysis supplies. The amount(s) at issue are in excess of five hundred and eighty-six thousand, five hundred and eighty-three dollars ($586,583.00).

HEARING TESTIMONY:

The Claimant's representatives explained that ERIKA, Inc., through the sales of its "Di-Ala-Kit" supplies more than 50% of all patients on home dialysis in the United States, through a convenient and single source of supply. In order to perform a dialysis treatment approximately thirty different items are required. ERIKA purchases these supplies from various manufacturers in large quantities and accumulates the merchandise in its warehouses throughout the United States. Based on the patient's individual prescription, they break cartons into the required quantities and ship a "Di-Ala-Kit" containing the patient's exact requirements for 24 treatments on a standard eight week schedule.

ERIKA is reimbursed by the Carrier under Part B, the "Customary and Prevailing Charge" method. The claimant contended this method of reimbursement was primarily designed for physicians and other providers of services rather than distributors of supplies. Under this method the intermediary sets a charge screen based on the average of the prior years' actual invoices from the various providers in its geographic area. ERIKA is the only provider of its type in New Jersey and therefore, their prices determine the "screen".

ERIKA is a distributor of approximately 5,000 products from over 400 manufacturers, performing only ware-housing, packaging, distribution and customer service functions, and must be permitted to pass on price increases charged to ERIKA by the manufacturer, over which it has no control. Because of widespread inflation during the past several years, ERIKA has experienced a series of substantial price increase as well as an increase in its own operating costs. Without an opportunity to pass along these increases, ERIKA is required to provide this merchandise to patients at prices which do not allegedly even cover their cost prices. Since this situation is apparently unique and unforeseen in the regulations, the Claimant is requesting an adjustment to the "screen" method(s) used by the Carrier.

The Claimant testified that ERIKA relates to its status as a seller of medical supplies and equipment used by patients undergoing kidney maintenance dialysis in a home setting . . . who are self-dialysing at home. Allegedly, pursuant to Intermediary Letter 73-25, the method of calculating both the customary and prevailing charge(s) for ERIKA's reimbursement is intended to be covered by the normal reasonable charge rules rather than by the special rules estab-

lished for physicians' services. Analyzing the methodology that should apply to ERIKA's reimbursement should be the controlling regulations which govern the criteria for the determination of reasonable charges.

Therefore, if the methodology applied to ERIKA is analyzed in the light of the normal reasonable charge regulations, adjustments upward should have been made in the amount of reimbursement to ERIKA to reflect changes in the customary charge, and accordingly changes in the prevailing charges.. ERIKA's volume of activity within the geographic area served and used by the Carrier in determining prevailing charge(s) is sufficiently great that ERIKA constitutes both the customary and the prevailing charge(s) for the great majority of the supplies and equipment which are germaine to this present Hearing.

This anomaly results when ERIKA experiences increases from its suppliers, which would normally be reflected in the market place uniformly, and constitutes new prevailing charges, they are reflected as new customary charges for ERIKA and are controlled by the then existing prevailing charge(s), which is the previous customary charge of ERIKA. The Claimant contended there is substantial flexibility in the Medicare regulations governing reasonable charge(s), in addition to specific provisions within those regulations, that not only permit recalculation(s) of the charge limits for the reasonable charge for ERIKA and permits many of the increases it receives, which are an expected part of the process of calculating customary and prevailing charges.

It was testified that ERIKA supplies approximately fifty percent of Medicare patients, whereas, the remaining fifty percent are "private pay patients". The

Claimant periodically supplies the Carrier with supplements and amendments to their catalog, which reflect their price adjustments they are charging their "private pay patients". They contended that this notification to the Carrier constituted factual information that should have served as a basis for an adjustment in both the customary charge and the revaluation of the prevailing charge(s).

The Claimant characterized their "reseller status" as meaning that much of the equipment and supplies which it sells is purchased in manufactured forms from other unrelated companies, many of whom sell in the same general product market, although not necessarily in the same geographic market.

The Claimant contended that Section 1842-D of the Social Security Act . . . "has specific reference to the fact that in the case of medical services supplied and equipment charges incurred after December 31, 1972 determined to be reasonable, may not exceed the lowest charge levels when such services and equipment are widely available in a locality, except to the extent and under circumstances interpreted by the Secretary". The Claimant contended it makes reference to the fact of using comparable services supplied and equipment—and it authorizes the Secretary to vary that limit upward, if necessary, to reflect local conditions. Furthermore, Section 405.506 specifically contemplates the possibility of charges higher than the customary or prevailing charges.

The Claimant also contended that they had supplied sufficient information to the Carrier which, pursuant to applicable regulations, authorized the Carrier to adjust the customary charges of ERIKA, and

accordingly, the prevailing charges based on that factual information, reflected changes in the customary and prevailing charges within the market place, which revaluations are encouraged by the regulations. The Claimant specifically contended . . . "We don't believe that anything we are asking for requires the Carrier to go outside the present language of the regulations". Whereas, the Carrier consistently contended . . . "The Bureau has consistently told us to hold to the regulations which discuss customary and prevailing and revaluation on an annual basis".

The Claimant denied requesting carte blanche authority to present any price increases they receive to the Carrier, but rather there are circumstances when the right evidence is available and warrants the Carrier to make a determination other than at the calendar anniversary as to whether or not a particular customary or prevailing charge has changed and to respond to it. The Claimant contended there is both authority and encouragement to examine the circumstances during various intervals in the existing regulations which might support a change in the customary and prevailing charge(s). They alleged that the magnitude of review and verification is not a rationale for not doing it.

The Carrier respresentatives explained that reimbursement to suppliers is usually made on the basis of reasonable charge, which is determined by the customary charge of the supplier and the prevailing charge in a locality.

Medicare regulations specified that Carrier prevailing charge screens for any July through June period may not exceed the 75th percentiles of customary charges for the services in the preceding calendar year. Once

customary charge screens have been established for a year, further increases (other than to correct mathematical errors made in the calculation of prevailing charge amounts) are permitted only in individually identified and highly unusual situations where equity clearly indicates that increases are warranted. The law established the manner in which prevailing charges are to be calculated precisely as it does, the equity adjustment provision is applicable only to customary charges. Current costs and currently charged prices for supplies cannot be considered by the Carrier in their prevailing charge calculations. Under the established reimbursement criteria, established prevailing charge screens must govern, unless it can be determined that the Carrier improperly obtained base year charge data or committed mathematical errors in the calculation of prevailing charge amounts. The Carrier has no authority to revise prevailing charges or base them on current year charges.

APPLICABLE LAW, REGULATIONS AND GUIDELINES:

Title XVIII, Health Insurance for the Aged, and Public Law 89-97 of the Social Security Act, as amended, and quoted in part, provides:

> *Section 1842(a)* In order to provide for the administration of the benefits under this part . . . the Secretary is authorized to enter into contracts with Carriers . . . which will . . . (1) (A) make determinations of the rates and amounts of payment required pursuant to this part to be made to providers of services . . . on a . . . reasonable charge basis . . . (3) Each contract shall provide that the Carrier . . . (b) will take such

action as may be necessary to assure that, where payment under this part for a service is on a charge basis, such charge will be reasonable . . . (E) . . . there shall be taken into consideration the customary charges for similar services generally made by the physician or other person furnishing such services, as well as the prevailing charges in the locality for similar services.

Section 1871 The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title . . .

The Department of Health, Education and Welfare of Social Security provides all Carriers with a Medicare Part B Carrier's Manual, as an aid in the processing of claims. The following Sections, as amended, and quoted in part, provides:

25 DURABLE MEDICAL EQUIPMENT

25-1 HEMODIALYSIS EQUIPMENT—HOME USE

The following conditions must be met before payment can be made for the home use of such equipment:

1. The device is required because the patient had end-stage renal disease.
2. The equipment is appropriate for home use. There are various types of dialysate delivery systems which supply dialysis fluid to the dialyzers which contain the blood. Approved units are those dialyzers and dialysis delivery systems prescribed by recognized specialists at approved home hemodialysis training centers where the patients are trained.

Section 2100. DURABLE MEDICAL EQUIPMENT—GENERAL

Expenses incurred by a beneficiary for the rental or purchase of durable medical equipment (DME) are reimbursable if the following three requirements are met. The decision whether to rent or purchase an item or equipment resides with the beneficiary.

A. The equipment meets the definition of DME (Section 2100.1); and

B. The equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the function of his malformed body member (Section 2100.2);

C. The equipment is used in the patient's home (Section 2100.3).
and

Chronic Renal Disease

Section 2230. TREATMENT OF CHRONIC RENAL DISEASE

Section 2231.1 Definition of Terms.—

A. *Chronic Renal Disease (CRD).*—Terminology—The term "end-stage renal disease" is the technically accurate term for that stage of chronic renal disease which requires a continuing course of dialysis or kidney transplantation to ameliorate uremic symptoms and maintain life. The term "chronic renal disease" alone does not describe this stage of renal disease completely because many chronic renal conditions do not require maintenance dialysis or kidney trans-

plant; however, the term end-stage may connote a terminal condition to patients not familiar with this language. The term chronic renal disease (CRD) is therefore, used in this manual with the understanding that in this context the reference is to chronic renal disease which requires hemodialysis or transplantation, as set out in the law. In correspondence with the public, it is recommended that a term such as "permanent kidney failure" be used, or "chronic renal disease," with the qualifying language of the law.

B. *Dialysis.*—A process by which waste products are removed from the body by diffusion from one fluid compartment to another across a semipermeable membrane. There are two types of renal dialysis in common clinical usage, hemodialysis and peritoneal dialysis are acceptable modes of treatment of chronic renal disease.

1. *Hemodialysis.*—Where blood is passed through an artificial kidney machine and the waste products diffuse across a man-made membrane into bath solution known as dialysate after which the cleansed blood is returned to the patient's body.

2. *Peritoneal Dialysis.*—Where the waste products pass from the patient's body through the peritoneal membrane into the peritoneal (abdominal) cavity where the bath solution (dialysate) is introduced and removed periodically.

Section 5000. Reasonable Charges as a Basis for Payments

The reasonable charge is the basis of payments under the supplementary medical insurance program for medical and other health services furnished by physicians, medical groups, independent laboratories, suppliers of ambulance services, and suppliers of durable medical equipment, prostheses, etc.

In the administration of the medical insurance program, the Carrier has primary responsibility for determining reasonable charges. The careful determination of reasonable charges in a way which is equitable both to those rendering the services and to those paying the premiums is a very important responsibility. The possible impact on fees charged and general public is a matter of broad concern that should be considered in applying the criteria for determining reasonable charges. The amount of future premiums under the medical insurance program will be directly affected by Carrier performance in determining reasonable charges.

The reasonable charge determinations made by Carriers are not normally reviewed by the Bureau of Health Insurance on a case-by-case basis. However, the Bureau of Health Insurance has an overall responsibility for the administration of the supplementary medical insurance program. The basic methods and procedures used by Carriers in determining reasonable charges must therefore, be consistent with the law, the regulations, and the broad principles and policy guidelines issued.

The following guidelines are intended to assure overall consistency among Carriers with respect to the concepts they apply in making reasonable charge determinations.

Section 5002. CRITERIA FOR DETERMINING A A REASONABLE CHARGE

The two criteria set out in the Medicare law (Section 1842 of title XVIII) which must be considered in determining the reasonable charge for a service are: (a) *the customary charges* for similar services generally made by the physician or other person furnishing such services; and (b) *the prevailing charges* in the locality for similar services.

Therefore, the reasonable charge for a specific service (Section 5030.2), in the absence of unusual medical complications or circumstances (see Section 5024 and 5200ff.) may not exceed the lowest of: (a) the physician's or other person's customary charge for that service; (b) the prevailing charge made for similar services in the locality (however, see Section 5020.3); or (c) the actual charge of the physician or other person rendering the service (Section 5030).

The law also provides that the reasonable charge for a service may not exceed the charge applicable for a comparable service and under comparable circumstances to the policyholders or subscribers of the Carrier. (See Section 5026)

Also, under the law, other factors that may be found necessary and appropriate with respect to a specific item or service to use in judging

whether the charge is inherently reasonable, should be taken into account.

The income of the individual patient may not be considered in determining the amount of the reasonable charge. Consideration of a patient's income in determining the reasonable charge could be looked upon as an inverse means test—that is, it would result in a situation under which the Medicare program would pay more for beneficiaries with high incomes than it would pay for beneficiaries with low incomes. There is no provision in the Medicare law for a Carrier to evaluate the reasonableness of charges in light of an individual beneficiary's economic status.

Section 5002.1 General Updating of Customary and Prevailing Charges.—

The customary and prevailing charge limits used by the Carriers should be *updated as early as possible at the beginning of each fiscal year (the 12-month period beginning July)*, using the available statistics on charge physicians and other persons have made for services derived from claims processed or from claims for services rendered during all of the immediately preceding calendar year. For example, the limits used during fiscal year 1972 (July 1, 1971 - June 30, 1972) were based on the charges made in calendar year 1970.

Before changes in reasonable charge screens can be implemented, the appropriate RO will, based on the data which it has reviewed and analyzed, notify the Carrier in writing as to whether or

not the screens are found acceptable. Final decision on any questions regarding the implementation of new screens will need to be made on an individual Carrier basis by the Bureau of Health Insurance.

Once the Carrier has made a general update of its customary and prevailing charge screens for a fiscal year, further revisions in these screens will not be permitted, during that fiscal year, except (1) as outlined in Section 5010.2; or (2) to correct erroneous calculations; or (3) to establish screens for new physicians/suppliers or new services. In no event may a corrected locality prevailing charge exceed the amount justified by the maximum allowable prevailing charge (calculated in accordance with Section 5020.3C), the no-rollback provision, and/or the Administrative Savings Clause. (See Section 5020.3E)

All date on the frequency of services, all data files and customary and prevailing charge files used to establish reasonable charge screens should be retained by the Carriers and be available for use, e.g., in implementing the economic index limitation on prevailing charges. It is especially important to retain the data for calendar year 1971 since this is the base year for applying the economic index limitation on prevailing charge increases.

Section 5010. THE CUSTOMARY CHARGE

The customary charge is the amount which best represents the actual charges made for a given medical service by a physician to his patients in general, or by other persons who supply other medical and health services to the general public.

The Carrier should therefore, obtain information on the customary charges of physicians and other persons not only from the Medicare Program, but from other available sources, e.g., from its own programs, from other insurance programs, from the Federal Employee Health Benefit Program, from CHAMPUS, from any studies conducted by State or local medical societies, and from public agencies. It also may ask physicians or other persons for their charges for services rendered to the public in general where the Carrier decides that circumstances will permit this.

In instances where physicians or other persons may feel that the Carrier does not have sufficient current information about their charges, they may volunteer this information to the Carrier. Further, Carriers should make known to the medical community their willingness to receive currently valid information regarding customary charges. However, any information on charges obtained from other sources should be validated, to the extent possible, against the Carrier's claims experience under Medicare and its own programs.

Section 5010. CALCULATING THE CUSTOMARY CHARGE.—

To the extent possible, when customary charges are calculated for a fiscal year, the actual charges physicians or other persons have made for services rendered during the calendar year immediately preceding the start of the fiscal year (i.e., derived from *either* claims processed, *or* from claims for services rendered during the preceding calendar year) must be used.

In calculating the customary charge for a given service, each charge the physician or other person has made for a service should be arrayed in ascending order. The lowest actual charge which is high enough to include the median of the arrayed charge data should then be selected as the physician's or other persons customary charge for the service.

However, where the charge generally made by a physician or other person to other patients are lower than those made to Medicare beneficiaries, the lower charges should be used as the basis for establishing the Medicare reasonable charge screen.

In order to accurately reflect a physician's customary charging pattern, the Carrier should establish a minimum number of charges for the same service, i.e., three charges where two are identical, or four charges where each is different, in order to calculate a customary charge for that service. Carriers may apply other criteria where necessary in a particular case, but only with regional office approval.

When a Carrier does not have adequate statistics on charges for all of a calendar year, e.g., for suppliers of medical equipment, prosthetics, ambulance services, or for new services, the fees charged and the price lists in effect as of June 30 of that calendar year only may be used. The intent is to use a price list which can reasonably be assumed not to exceed the median of the prices charged by the supplier for his items and services during the calendar year.

Where a Carrier has permitted an increase in a customary charge under the unusual circumstances provision (See Section 5010.2), the increased amount should be recognized as the customary charge for the next fiscal year if it exceeds the median of the charges made by the physician or other person for the service during the calendar year immediately preceding the start of that fiscal year.

Section 5010.2 Equity Adjustments in Customary Charge Screens.—

Once a Carrier has established the customary charge screens for a fiscal year, further increases (other than to correct errors) will be permitted only in individually identified and highly unusual situations where equity clearly indicates that the increases are warranted. Request for revisions in customary charge profiles should be initiated only by physicians or other persons furnishing covered services. Such requests should be neither encouraged nor discouraged by the Carrier, and each request will have to be handled on the basis of its own merits. Generally, each Carrier has the responsibility for determining whether an equity adjustment in a physician's or other person's customary charge profile can be made. In each instance in which an adjustment is made, the Carrier must document the situation and its determination, and have such documentation readily available for review by the Bureau of Health Insurance. Normally, equity adjustments should be made in customary charge profiles only in a relatively small number of situations.

Section 5020. Determining the Prevailing Charge

Prevailing charges are those charges which fall within the range of charges that are most frequently and widely used in a locality for a particular procedure or service. The top of this range establishes an overall limitation on the charges which the Carrier should accept as reasonable for a given procedure or service, except where unusual circumstances or medical complications warrant an additional charge (Section 5024).

For any fiscal year, the prevailing charge limit in a locality for a service must be calculated as the 75th percentile of the customary charges determined for that service in accordance with Section 5010.1. (However, see Section 5020.3 regarding the economic index limitation). In this calculation, each customary charge for the service should be arrayed in ascending order and weighted by how often the physician or other person rendered the service (as reflected by the charge data the Carrier used to calculate the customary charge). The lowest customary charge which is high enough to include the customary charges of the physicians or other persons who rendered 75 percent of the cumulative services is then to be determined as the prevailing charge for the service (subject to the economic index limitation).

Section 5020.1 Determination of Locality

For the purpose of making reasonable charge determinations, a locality is the geographic area for

which the Carrier is to derive the prevailing charges for services, usually a locality will be a political or economic subdivision of a State, and it should include a cross-section of the population with respect to economic and other characteristics. Where people tend to gravitate toward certain population centers to obtain medical care or service, localities may be recognized on a basis constituting medical service area (interstate or otherwise), comparable in concept to "trade areas".

Carriers should delineate localities on the basis of their knowledge of local conditions. The localities may differ in population density, economic level, and other major factors affecting charges for services. However, distinctions between localities should not be so finely made that a locality includes only a very limited geographic area whose population has distinctly similar income characteristics (e.g., a very rich or very poor neighborhood within a city).

Section 5100. OTHER HEALTH AND MEDICAL SERVICES

The supplementary medical insurance program provides for reimbursement on a reasonable charge basis for other medical services and items listed in Section 2000ff.

Instructions pertaining particularly to the determination of reasonable charges for covered items and services will be developed, as necessary and included in this chapter. However, the guides for the determination of reasonable charges and the statutory requirement that reasonable

charges determined on the basis of the applicable customary and prevailing charge criteria also apply to these items and services.

Section 5100.1 Determining Reasonable Charge for Packaged Dialysis Supplies.

In making this determination, the Carrier should compare the package charge to the charge for covered individual package components from the *same* supplier. If the total for covered items would entitle purchaser to a quantity discount in the supplier's traditional manner of doing business the discount should be subtracted. Where the supplier provides only packages and has no individual item charges, the Carrier should use its own discretion in selecting charge data from other suppliers for use in making the charge determination.

The following Regulations of the Secretary of Health, Education and Welfare, promulgated for the Administration of Supplementary Medical Insurance Program, as amended and quoted in part, provides:

405.501.. Determination of Reasonable Charges.

Payment for medical and other health services (See Section 405.251) furnished by physicians or other persons (except for services furnished by group practice prepayment plans electing cost reimbursement and certain services furnished by, or under arrangements made by, a provider of services) is made on the basis of the "reasonable charge" for such service which is determined by the Carriers selected by the Secretary to assist in the administration of the supplementary medical insurance program.

405.502 Criteria for Determining Reasonable Charges.—

(a) Criteria.—The law does not contemplate the establishment of a general fee schedule applicable to all physicians or other persons furnishing medical and other services but calls for individual determinations which take into account the facts as to existing practice with respect to charges of the particular physician or other person as well as others in the locality. The two criteria set out in the law which are considered in determining reasonable charges are:

(1) The *customary charges* for similar services generally made by the physician or other person furnishing such services; and

(2) The *prevailing charges* in the locality for similar services.

405.503 Determining Customary Charges.

—(a) Customary Charge Defined.—The term "customary charges" will refer to the uniform amount which the individual physician or other person charges in the majority of cases for a specific medical procedure or service.

—(d) Revision of Customary Charge.—A physician's or other person's customary charge is not necessarily a static amount. Where a physician or other person alters his charges, a revised pattern of charges for his services may develop. Where on the basis of adequate evidence, the Carrier finds that the physician or other person furnishing services has changed his charge for a service to the public in general, the customary

charge resulting from the revised charge for the service should be recognized as the customary charge in making determinations of reasonable charges for such service when rendered thereafter to supplementary insurance beneficiaries. *If the new customary charge is not above the top of the range of prevailing charges (See Section 405.504(a)), it should be deemed to be reasonable by the Carrier,* subject to the provisions of Section 405.508.

405.504 Determining Prevailing Charges.—

(a) Range of Charges.—The term "prevailing charges" refers to those charges which fall within the range of charges most frequently and most widely used in a locality for particular medical procedures or services. The top of this range establishes, except as provided in Section 405.506, an overall limitation on the charges which a Carrier will accept as reasonable for a given medical procedure or service. Prevailing charges are derived from the overall pattern existing within a locality. For example, in a given locality the Carrier may find that the charges most frequently and widely used by physicians for a particular medical procedure range from $150 to $175. If in another locality the Carrier finds that the prevailing charges are different for the same procedure, then a different range of charges would be applied in making reasonable charge determinations for that locality. An acceptable method for the Carrier to objectively determine the point at which such limitation is established would be the use of the mean (arithmetic average) of the customary charges of physicians or

other persons in the locality for a given medical procedure or service, plus one standard deviation above the mean, rounded to the nearest dollar. However, the Carrier will adopt an appropriate limit for each procedure or service with judgment being exercised to assure that with respect to each particular array of data the result reached is reasonable. If, for example, there is a point just above the standard deviation which represents the amount charged by a substantial number of physicians in the locality, the limitation might, in such a situation, be established so as to include this point. On the other hand, the "trailing off" of an appreciable number of charges above the mean plus one standard deviation might not justify an upward adjustment.

The "standard deviation" is a basic statistical measure widely used in dealing with variations from a central tendency or norm. Its advantage over the approach that the "prevailing charge" is to include a fixed percentage of all charges lies in the fact that the standard deviation is flexible rather than rigid. It takes into account and is responsive to differences in the spread that exists in the underlying data.

(b) Variation in Range of Prevailing Charges. —The range of prevailing charges in a locality may be different for physicians or other persons who engage in a specialty practice or service than for others. Existing differentials in the level of charges between different kinds of practice or service could, in some localities, lead to the development of more than one range of prevailing charges for application by the Carrier in

its determinations of reasonable charges. Carrier decisions in this respect should be responsive to the existing patterns of charges by physicians and other persons who render covered services, and should establish differentials in the levels of charges between different kinds of practice or service only where in accord with such patterns.

(c) Reevaluation and Adjustment of Prevailing Charges.—Determinations of prevailing charges by the Carrier are to be reevaluated and adjusted from time to time on the basis of factual information about the charges made by physicians and other persons to the public in general. This information should be obtained from all possible sources including a Carrier's experience with its own programs as well as with the supplementary medical insurance program.

405.505 Determination of "Locality".—

"Locality" is the geographical area for which the Carrier is to derive the prevailing charges for services. Usually, a locality will be a political or economic subdivision of a State. It should include a cross section of the population with respect to economic and other characteristics. Where people tend to gravitate toward certain population centers to obtain medical care or service, localities may be recognized on a basis constituting medical service areas (interstate or otherwise), comparable in concept to "trade areas". Localities may differ in population density, economic level, and other major factors affecting charges for services. Carriers therefore, shall delineate "localities" on the basis of their knowledge of local conditions. However, distinctions between

localities are not to be so finely made that a "locality" includes only a very limited geographic area whose population has distinctly similar income characteristics (e.g., a very rich or very poor neighborhood within a city).

405.506 Charges Higher Than Customary or Prevailing Charges.—A charge which exceeds either the customary charge of the physician or other person who rendered the medical or other health service, or the prevailing charge in the locality, or both, may be found to be reasonable, but only where there are unusual circumstances, or medical complications requiring additional charge, and only if it is acceptable medical or medical service practice in the locality to make an extra charge in such cases. On the other hand, the mere fact that the physician's or other person's customary charge is higher than prevailing would not justify a determination of reasonable charge higher than the prevailing charge.

405.508 Determination of Comparable Circumstances; Limitation.—(a) Application of Limitation.—The Carrier may not in any case make a determination of reasonable charge which would be higher than the charge upon which it would base payment to its own policyholders for a comparable service in comparable circumstances. The charge upon which it would base payment, however, does not necessarily mean the amount the Carrier would be obligated to pay. Under certain circumstances, some Carriers pay amounts on behalf of individuals who are their policyholders, which are below the customary charges of physicians or other persons to other individu-

als. Payment under the supplementary medical insurance program would not be limited to these lower amounts.

(b) When Comparability Exists.—"Comparable circumstances," as used in the Act and this subpart, refers to the circumstances under which services are rendered to individuals and the nature of the Carrier's health insurance programs and the method it uses to determine the amounts of payments under these programs. Generally, comparability would exist where:

(1) The Carrier bases payment under its program on the customary charges, as presently constituted, of physicians or other persons and on current prevailing charges in a locality, and

(2) The determination does not preclude recognition of factors such as specialty status and unusual circumstances which affect the amount charged for a service.

(c) Responsibility for Determining Comparability.—Responsibility for determining whether or not a Carrier's program has comparability will in the first instance fall upon the Carrier in reporting pertinent information about its programs to the Social Security Administration. When the pertinent information has been reported, the Social Security Administration will advise the Carrier whether any of its programs have comparability.

Responding to an ERIKA, Inc. request for an equity increase and/or adjustment for split home dialysis kits and other dialysis supplies; on June 14, 1977,

Mr. Henry J. Hehir, Director, Provider and Medical Services Policy, Bureau of Health Insurance, Social Security Administration, at Baltimore, Maryland, wrote Joseph E. Casson, Esquire, Counsel for ERIKA, Inc. (in part) as follows:

"In an exchange of correspondence (copies enclosed) between our New York health insurance regional office and ERIKA on this issue in 1976, Mr. Savario De Bosa explained the statutory constraints that are imposed on prevailing (illegible) levels, once they are established each July 1. He also noted that once customary charge screens are established, further increases (except to correct obvious errors) are permitted only in individually identified and highly unusual situations where equity clearly indicates that the increases are warranted. Since Mr. De Rosa did not furnish particulars on equity adjustments for customary charges, I am enclosing a copy of the policy guidelines Carriers are required to follow when determining whether such an increase is warranted. However, it *should be understood that any increases in the customary charge screens for ERIKA's supplies would not affect the current program payments it presently receives. The reason for this is that the established customary charges for ERIKA's various supplies are equal to the prevailing charges for these items. And, as you know, the prevailing charge levels set the program reimbursement limits for covered medical services and supplies under Part B of Medicare.*

Our understanding of the alternative method of payment you discussed with Mr. Pyles is illustrated by the following:

Example

A supplier charges a patient $700 for a dialysis kit containing five covered items for which the total Medicare reasonable charge, if the items were purchased separately, would be $800. When processing the claim for the kit, the Medicare Carrier determines that $700 is the reasonable charge for the kit. On the next shipment, the supplier sends only four of the five covered items, and the reasonable charge is determined to be $600 (based on the total reasonable charges that can be allowed for the four items when purchased separately).

Under your suggested alternative, since the reasonable charge for the omitted item when purchased individually ($200) was equal to one-fourth of the total reasonable charge for *all* items when purchased individually ($800), a "reasonable charge" of $625 for the "broken" kit would be derived. This would be done by reducing the $800 by the product of one-fourth of the kit price ($800 minus ¼ x $700 = $800 — $175 = $625).

The amount resulting from the calculation illustrated above exceeds (by $25 in the example) the sum of the reasonable charges for the covered items actually included in the "broken" kit and, therefore, could not be allowed under the provisions of section 1842(b)(3) of the Medicare law. We should also add that if the Carrier were to determine the reasonable charge for a "broken" kit by making proportional adjustments in the reasonable charge for the basic kit, the amounts allowed would be less than Prudential is currently allowing your client. In the above example, it could be reasoned that since the basic kit

had a reasonable charge of $700 and the item omitted was equal to one-fourth of the reasonable charge for all five items, the reasonable charge for the "broken" kit would be $800 minus one-fourth of $700, or $525. The following discussion should help you to understand the guidelines Carriers use in determining the reasonable charge for a dialysis kit.

Supplies such as dializers, venous and arterial sets, dialysate, saline solutions, administration sets, fistula needles and Heparin are covered items when required for the effective operation of a home dialysis machine. Conversely, supplies not necessary for the operation of the machine (even though they are necessary for the patient's well being) such as syringes, alcohol wipes, adhesive tape, bandages, alcohol, betadine, and underpads are generally noncovered items. *However, regardless of whether such noncovered items are included in a package with covered items, the reasonable charge for Medicare reimbursement purposes will be the lesser of the total of individual reasonable charges for all covered items in the package when purchases* [sic] *separately in comparable quantities, or the package charge. This rule applies whether the package (kit) is "broken" or not.*

In making this determination, the Carrier will compare the package charge to the reasonable charges for covered individual package components from the *same* supplier. If the total for covered items would entitle purchasers to a quantity discount in the supplier's traditional manner of doing business, the discount is subtracted. Where the supplier provides only packages and has no individual item charges, the Carrier will use its own discretion in selecting charge data from other suppliers for use in making the charge determination.

As an example of a package of home dialysis supplies for a 2-month period . . . the supplier's charge of $705 for the package in this instance is less than the sum of charges for individual covered components if purchased separately and, hence, is the reasonable charge.

The objective underlying the above rule was to assure that the beneficiary would be able to receive from one source all the necessary items in a single shipment that would be needed in performing the vital home dialysis treatments over a period of time, e.g., 2 to 3 months. It was anticipated that shipments in this fashion would enable the suppliers to realize cost savings which they could pass along to the beneficiary in the form of a single, package rate. And, once the reasonable charge for the basic package of supplies or kit was established, it would be administratively easy for a Carrier to process the subsequent claims for the basic kit. However, as we have indicated above, whether the basic dialysis supply kit is broken, or not, the reasonable charge cannot exceed the total amount that would have been determined to be reasonably by the Carrier if the individual *covered* items it contains had been furnished to the patient on an individual item basis.

I trust this explanation will help clarify the reasonable charge rules as they are applied to the pricing of both a basic dialysis supply kit and one that is "customized", i.e., "broken". I regret our statutory authority does not extend to the kind of pricing you suggest."

Addenda thereto, on November 10, 1976, in response to a request from Mr. Leonard A. Estin, Executive Vice President of ERIKA, for a change in

Medicare's current method of determining customary and prevailing charges for home dialysis supplies; Mr. Saverio De Rosa, Contractor Officer, of the Regional Bureau of Health Insurance in New York City, wrote the following response:

> "Medicare Law specifies that Carrier prevailing charge screens for any July through June period may not exceed the 75th percentiles of customary charges for services in the preceding calendar year. The law specifically defines the base year from which charge data will be derived for the purposes of calculating reasonable charges. Once customary charge screens have been established for a year, further increases (other than to correct mathematical errors made in the calculation of prevailing charge amounts) are permitted only in individually identified and highly unusual situations where equity clearly indicates that increases are warranted. However, since the law sets forth the manner in which prevailing charges are to be calculated as precisely as it does, the equity adjustment provision is applicable only to customary charges. Current costs and currently charged prices for supplies cannot be considered by the Carrier in their prevailing charge calculations. Thus, under the established reimbursement criteria, established prevailing charge screens must stand, unless it can be determined that the Carrier improperly obtained base year charge data or committed mathematical errors in the calculation of prevailing charge amounts. Therefore, the Carrier has no authority to revise prevailing charges or base them on current year charges.

CONCLUSION AND DECISION:

The Claimant's principle thrust in their challenging arguments to the Carrier's refusal to grant equity increases and/or adjustments would appear to be: (1) that a proper application of the rules and regulations of the Medicare Program require upward adjustments in both the customary and prevailing charges for ERIKA to reflect the increases in ERIKA's catalog prices; (2) that a sufficient non-Medicare market exists on which to predicate an accurate and current prevailing rate for ERIKA's products; (3) sufficient evidence has been presented to establish that ERIKA has increased its customary charge to its current catalog prices; and (4) that nothing in the Medicare rules and/or regulations operate to prevent these adjustments. Succinctly stated by ERIKA's counsel at the Hearing . . . "We don't believe that anything we are asking for requires the Carrier to go outside the present language of the regulations."

However, and pursuant to the very specific Medicare law, regulations and guidelines, hereinbefore outlined, and augmented by the written opinions of Mr. Henry J. Hehir, Director, and Mr. Saverio De Rosa, Contractor Officer, of the Bureau of Health Insurance; the criteria for Medicare reimbursement is the provider's customary or the prevailing fee, whichever is lower. Furthermore, once prevailing fees are established each year, they cannot be changed, unless an error in calculation is detected.

A valid prevailing fee usually requires at least five providers. However, exceptions can and were made in home renal dialysis supplied because: (1) ERIKA was and is the sole provider in the State of New

Jersey; (2) although other sources in New Jersey could be used, none were available; and (3) although there are similar providers nationwide, the Medicare law precludes establishing prevailing fees by sources outside New Jersey.

Therefore, prices in ERIKA's catalog were used for both customary and prevailing fees by the Carrier. Since reimbursement cannot exceed prevailing fees, and prevailing fees cannot be increased, the Carrier refused the Claimant's request for general increase in their supplies.

The Claimant had also apparently requested a revision of Medicare's reimbursement policy regarding their split kits of renal supplies, contending that the percentage be calculated of the charge for an omitted item to the total charge of all the components if purchased individually. The calculated percentage should be used in calculating the deduction for the omitted item from the package price. This would result in a greater allowance than under the present reimbursement method.

Part B Medicare regulations requires that the reasonable charge reimbursement must be the lesser of the total individual reasonable charge for all covered items in the package when purchased separately in comparable quantities, or the package charge. This rule applies whether or not the package is broken. If one eligible item is omitted from the package, that individual amount must be deducted from the package or kit cost.

The Hearing Officer has therefore, concluded, under the current Medicare law, regulations and guidelines, that the Carrier decided correctly in having denied the Claimant's request for an equity increase/adjust-

ments for home dialysis kits and other dialysis supplies. Pursuant to Section 405.860 (Authority of the Hearing Officer) of the Federal Regulations, the Hearing Officer hereby affirms and concurs with the Carrier's decision.

In accordance with Section 405.835 of the Federal Regulations, this decision is binding on all parties to this claim(s) and Hearing.

This is the seventh day of February, 1978.

HENRY A. HARTLEY
Hearing Officer

Exhibit 1 04/18/77—Letter from H. McCann, R.M., ERIKA to Mr. Risley, Medicare, requesting an increase in allowances for supplies for home renal dialysis beneficiaries.

Exhibit 2 04/27/77—Letter from H. McCann, R.M., ERIKA to Mr. Risley requesting increases in allowances for additional supplies (2).

Exhibit 3 05/03/77—Letter to Ms. McCann, ERIKA, for price information from Mrs. Willis, Medicare.

Exhibit 4 05/14/77—PRR referral for requested price information.

Exhibit 5 05/19/77—PRR reply—information will be furnished as soon as possible.

Exhibit 6 06/14/77—Letter from Ms. McCann to Mrs. Willis re: previous notice of increase to prevailing market price, our 5/3 letter, ERIKA's policy is to utilize the manufacturer's suggested resale price in their price determination.

Exhibit 7 06/14/77—Letter to Mr. Casson, Counsel for ERIKA, from Mr. H. Hehir, Director, Prov. and Med. Serv. Pol., BHI. Letter discusses:

1. Equity increase request—reply is that ERIKA's charges are prevailing and prevailing cannot be increased.

2. Alternative method of payments for kits suggested by ERIKA—would like percent of separate costs and subtract by that percent from the kit price. Per BHI guidelines—reimbursement must be the lesser of total individual charges or the "kit" price. Omitted items from the "kit" will be subtracted from the package price using individual charges by same supplier's price list for item omitted.

Exhibit 8 06/29/77—Letter from Mr. Casson to Medical Administration Division, Prudential—requesting fair hearing and mentioned claims filed with

Medicare for review of disallowed amounts on home dialysis (all had been returned to ERIKA). Fair hearing requested on grounds of delay in reviewing those claims (405.821 in regulations).

On 07/13/77, Mr. Risley called Mr. Casson to discuss letter—Mr. Casson indicated he wants to file suit against the government and before doing so, must go through Adm. Mr. Casson will send letter waiving right to informal review in order to expedite hearing process.

Exhibit 9 Letter to Ms. McCann, ERIKA, from Mrs. Willis, Medicare, in reply to her 06/14/77 letter criteria for determining Medicare's allowance is the lower of customary or the prevailing. Since their fees are equal to prevailing, no increase can be considered.

Exhibits 11-17 Exchange of correspondence between the Hearing Officer and ERIKA, Inc. legal counsel, re: scheduling a mutually convenient time and date for the Fair Hearing.

Exhibit 18 The Hearing Officer received (January 30, 1978) from Joseph E. Casson, Esquire, Counsel for ERIKA, Inc.:

(1) A copy of ERIKA's October 20, 1976 submission to The Prudential; and

(2) Copies of all regulatory and statutory provisions which Mr. Casson believes grants the Carrier sufficient authority to make the adjustments requested.

END OF LISTING.

APPENDIX G

EXCERPTS FROM THE MEDICARE CARRIER'S MANUAL

5010.1 *Calculating the Customary Charge.*—To the extent possible, when customary charges are calculated for a fee screen year, the actual charges physicians or other persons have made for services rendered during the calendar year immediately preceding the start of the fee screen year (i.e., derived from *either* claims processed *or* from claims for services rendered during the preceding calendar year) must be used.

In calculating the customary charge for a given service, each charge the physician or other person has made for a service should be arrayed in ascending order. The lowest actual charge which is high enough to include the median of the arrayed charge data should then be selected as the physician's or other person's customary charge for the service.

However, where the charges generally made by a physician or other person to other patients are lower than those made to Medicare beneficiaries, the lower charges should be used as the basis for establishing the Medicare reasonable charge screen.

The carrier should establish three charges as the minimum number of charges for the same service needed to calculate a customary charge for that service.

When a carrier does not have adequate statistics on charges for suppliers of medical equipment, prosthetics, ambulance services, or for new services, the fees charged and the price lists in effect as of June

30 of that calendar year only should be used. The intent is to use a price list which can reasonably be assumed not to exceed the median of the prices charged by the supplier for his items and services during the calendar year.

Where a carrier has permited an increase in a customary charge under the equity provision (see § 5010.2), the increased amount should be recognized as the customary charge for the next fee screen year if it exceeds the median of charges made by the physician or other person for the service during the calendar year immediately preceding the start of that fee screen year. The increased amount is the correct customary charge for use in the appropriate prevailing charge calculation(s).

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